Ethics and Confidentiality Committee (ECC) Meeting - Thursday 1 February 2012

Members:

Dr Mark Taylor (*acting Chair*), Mrs Pauline Brown, Dr Tony Calland, Dr Robert Carr, Dr Fiona Douglas, Ms Alison Emslie, Mr Colin Harper, Mr Stephen Hinde, Professor Julia Hippisley-Cox, Ms Gillian Wells, Mr Chris Wiltsher and Mr Terence Wiseman.

In attendance:

Dr Alan Doyle *(NIGB Director)(items 1-5a),* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Deputy Approvals Manager),* Mr Martin Frowd (*Senior Business Support Officer*), and Mr Sean Kirwan (*Department of Health*).

1. Welcome and apologies

Apologies were received from Dr Andrew Harris, Professor Michael Catchpole, Dr Tricia Cresswell and Dr Jane Kaye.

The Chair welcomed the new Members: Dr Robert Carr, Ms Alison Emslie, Ms Gillian Wells and Mr Chris Wiltsher. All Members briefly introduced themselves and their areas of interest and expertise.

Declarations of Interest

The following interests were declared:

a) Dr Fiona Douglas was not present in the room for the discussion and recommendation on item 5d as the applicant was a colleague.

b) Professor Julia Hippisley-Cox was not present in the room for the discussion and recommendation on item 5e as this item was in her area of research.

2. Minutes of last meeting [ECC 1-02(a)/2012] and matters arising

The minutes from the meetings held on 1 and 2 December 2011 were approved as an accurate record.

2a. Matters arising

Members were advised that the Committee had previously agreed that requests originating from the Office of National Statistics (ONS) Virtual Microdata Laboratory (VML) would be reviewed via fast track using a dedicated sub-group. The previous sub-group members had now left the Committee therefore a request for volunteers to take on this responsibility was made. Dr Tony Calland, Professor Julia Hippisley-Cox, Mr Chris Wiltsher and Mr Terence Wiseman volunteered to form this sub-group.

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

<u>February 2012 NIGB/ECC meeting</u>

The NIGB Director reminded the Committee that a joint Board/ECC session would be held in the morning part of the 23 February Board meeting, constituting a discussion between NIGB/ECC Members and the Health Research Authority, NHS Commissioning Board and Public Health England with respect to the future of functions currently carried out by the Committee. The Care Quality Commission would

now not be attending the 23 February meeting but discussions were continuing and now included the CQC's Department of Health sponsor.

Information Governance Toolkit incorporation into process

It had been previously reported that the DH policy position for those processing NHS data would be to complete the IG Toolkit as satisfactory evidence of the governance arrangements around the processing of confidential patient information for secondary uses. The implication for the ECC process would be to move from provision of a System Level Security Policy to seeking security assurance via an Information Governance Toolkit submission. Member comments had been fed through and clarity sought on what communications and support would be in place to advise applicants during this aspect of the process.

The NIGB Director updated the Committee on progressions since discussion with the Department of Health regarding completion of the Information Governance Toolkit by applicants. A phased approach to integration within the process would take place between April and September 2012, with a view to full rollout from October 2012, and the DH information governance policy team were setting up the team to manage queries. Members queried which version of the toolkit applicants would be expected to complete; Mr Kirwan was of the view it would be the Trust version, and this would be confirmed

Members were also informed that the NIGB had been carrying out an analysis of the toolkit scores with a predicted outcome to be a facilitated "buddy" system to encourage poorly performing organisations in each region to learn from the region's top performing organisations.

Secretary of State approval of applications

It was reported at the December meeting that in line with the construction of the Regulations, the Secretary of State for Health (SofS) would provide the final decision on whether an application should be approved or not (via a senior civil servant), taking into account advice provided by the NIGB Ethics and Confidentiality Committee. This would include extensions, amendments, fast track applications and annual reviews. Following the December meeting, it was confirmed that the SofS had accepted the advice provided by the Committee on all considered applications. It was acknowledged that this had the consequence of a small delay in the production of outcome letters due to requirement of final approval and that a revised timescale for final letters had been published.

Advice meeting

An introductory strategic meeting took place on Monday 09 January 2012 between the Department of Health, representatives from Public Health England and the National Commissioning Board. Dr Fiona Caldicott, Dr Andrew Harris, Dr Mark Taylor, Dr Alan Doyle, Mr Mathew Fry and Ms Natasha Dunkley attended as NIGB representatives.

The broad aim of the meeting had been to develop a shared understanding of current views and status in order to inform initial thoughts of the potential design of the process for managing advice in relation to research and non-research approvals. It was also an opportunity to talk through the key principles and learning of the Committee. This included discussion over the importance of ensuring appropriate expertise, independence, patient perceived trust in the system and technological advances in pseudonymisation. The importance of an appropriate exit strategy, operating a streamlined cohesive system and the context of the ECC improvement project were also highlighted.

Healthcare Quality Improvement Partnership (HQIP) meeting

Professor Sir Denis Pereira Gray, Ms Natasha Dunkley and Ms Claire Edgeworth had met with Robin Burgess, Chief Executive and Ms Helen Laing, Commissioning Manager as follow-up to an agreed action from the September 2011 Committee meeting. As HQIP commission many of the national clinical audits on behalf of the Department of Health (DH), and the Committee receives a number of audit applications that vary in the extent of identifiable data requested, it had been agreed that a meeting would take place to explore this with HQIP. It was noted that HQIP were uniquely placed to influence the

running of the audits, however, as their mandate comes from DH, HQIP proposed that their key role was to ensure contractual compliance and to make available a programme of training, of which the attendees were supportive. It was confirmed that HQIP publish general information on good practice within audits and run a programme of seminars on aspects such as data sharing and consent, and they have a significant role to play in influencing best practice via this communication channel. Prospectively efforts were made to ensure that compliance with information governance standards was placed on a contractual basis. All new audits were expected to demonstrate to HQIP why consent was not feasible, and HQIP would ensure they have sight of all applications prior to submission to the ECC.

National Institute of Cardiovascular Outcomes Research (NICOR) clinical leads meeting

Dr Andrew Harris, Professor Sir Denis Pereira Gray and Ms Claire Edgeworth met with the clinical leads of the NICOR audits in order to discuss the use of patient identifiable data within the audit applications. This meeting followed on from the outcome of the interim progress report submitted to the July 2011 Committee meeting. Representatives from the Medical Research Information Service (MRIS) also attended to discuss the services they could offer as a potential "broker" of identifiable information. Discussion focused on the ECC role in providing advice to the Secretary of State and the specific conditions that the Committee had set when reviewing the interim report in July 2011, including the confirmation of valid NHS number at point of submission and discussion around why 100% ascertainment would be required. NICOR reported that an estimated 0.1% of patients were allocated wrong NHS numbers within the audits and noted that NHS number could be checked using PDS but that demographic details would be required in the first instance in order to do this. Clinical leads asserted that for some audits there were particularly small numbers and in these cases 100% ascertainment would be of particular importance. In addition concerns were raised by NICOR that using NHS number only could potentially hinder the linkage of data between hospitals and with datasets where NHS number was not as prominent. Discussion around consent highlighted that in some audits patients would be particularly unwell and therefore consent would be difficult; clinical leads were informed that whilst these assertions were valid, consent should still be explored where possible with those who were well enough.

It was agreed that the separate audit applications to be submitted to the Committee in March 2012 would be of particular value, as these would allow the issues of pseudonymisation, the role of MRIS and consent to be explored in further detail for each individual cohort.

NHS Future Forum

The NIGB Director noted that the NHS Future Forum report and the government response had been published and circulated, and undertook to keep the Committee informed of significant developments.

Fast Track applications

This section sets out a summary of applications considered via fast track procedure. All applications that receive a provisional recommendation of support are required to receive confirmation of satisfactory security arrangements from the Department of Health's information governance team. Research applications must also receive a favourable opinion from an appropriate research ethics committee.

ECC 1-02 (FT2) 2012 Prognostic factors in end of life in COPD patients in Bristol

This application from the University Hospital Bristol, NHS Foundation Trust set out proposals to carry out research to retrospectively investigate the time lag between patients meeting prognostic factors that would influence life expectancy and the point of death in patients with chronic obstructive pulmonary disease (COPD).

A recommendation for classes one and six support was requested to provide a legitimate basis for researchers to access deceased patient identifiable information without consent from hospital and GP notes to collect name, NHS Number, hospital ID, GP registration, sex, date of birth and date of death of patients who died from COPD between 2005 and 2011. The applicant intended to access the data of 600 COPD patients with the expectation to analyse data of 400 COPD patients.

Following consideration of this application through the ECC fast track process (category two 'access to deceased patient information only') Members had requested further clarification on the retention period and extent of confidential patient information requested, compliance with the Data Protection Act 1998 (DPA) principles and extent of patient involvement.

After reviewing the responses, the Committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State for Health, subject to specific conditions of support. These conditions were to ensure compliance with fair processing principle of the DPA and to inform GP Practices that dissent should be respected. The applicant should provide details of the consultation outcome with the British Lung Foundation and any other patient involvement to the NIGB Office; confirmation of a favourable REC opinion and of satisfactory security arrangements.

ECC 1-02(FT3)/2012 EPICure 2 Outcomes for births before 27 weeks gestation in England

This research application from University College London outlined proposals for a study comparing two cohorts of children born in England in 1995 and 2006. Related to a previously approved application [PIAG 3-07(f)/2005], the principal objective of the study was to identify factors related to an apparent increase of 15% in births and 40% in the number of admissions of children with less than 26 weeks gestational age at birth. The linkage of two data sets previously collected by EPICure 1995 study and EPICure-2 2006 study with Hospital Episodes Statistics (HES) data would permit a detailed exploration of socioeconomic and demographic factors. In order to do so the applicant requested access to all births recorded within HES for the years 1995 and 2006, with the intention of validating the data and evaluating HES for this type of activity in future. A recommendation of support under the Regulations was sought so that patient identifiable information of mother and baby could be used to match the datasets with HES, namely NHS number, date of birth, date of death, postcode, gender, ethnicity, hospital of birth and hospital ID.

Following consideration of this application through the fast track process (category five - 'Applications only requiring time-limited access to undertake record linkage and validation and then pseudonymising the data') the Committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State for Health, subject to specific conditions of support. These were to securely destroy HES identifiable information not related to the EPICure datasets as soon as data linkage was completed (not exceeding the 6 months retention period). The retention period for other patient identifiable information should not exceed three years.

ECC 1-02(FT4)/2012 Describing Acute Kidney Injury in the Community

This research application from East Kent Hospitals University NHS Foundation Trust set out details of a study to describe the incidence of Acute Kidney Injury (AKI) in East Kent not associated with hospitalisation. Patients who had a serum creatinine measurement from 1st February 2009 to 31 July 2009 in East Kent would be included in the study (cohort of 107,000 patients).

Eligible patients would be identified in the pathology database by the Computer Database Manager. A recommendation for class one, four, five and six support was requested to provide a legitimate basis for researchers to collect patient NHS number, date of birth, date of death, sector level postcode and gender. This data would then be matched with the hospital database for admissions to hospital and with the SeiK (System for the early identification of Kidney Disease) Database. Subsequently, each patient would be assigned a unique identifier number and the NHS Number would be kept in a separate database from the research project database. NHS Number would be stored and archived after the study had ended.

Following consideration of this application through the fast track process (category five - 'Applications only requiring time-limited access to undertake record linkage and validation and then pseudonymising the data') the Committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State for Health,

subject to specific conditions of support. These were to receive/collect month and year of birth (or year of birth only) instead of full date of birth and to ensure compliance with the first and sixth principles of the DPA Confirmation was also sought that the NHS Number Database would not be accessed by researchers after linkage and pseudonymisation had taken place.

ECC 1-02 (FT5)/2012 Diagnosis of Abusive Head Trauma

This research application from the University Hospital of Wales NHS Foundation Trust proposed to collect data of all infants less than three years of age admitted to the University Hospital of Wales with head injuries or subdural haemorrhages, intracranial injury identified on neuroimaging, at surgery or at post mortem. The researcher would be notified by health professionals at the Hospital when a case occurred.

A recommendation for class one, four and six support was requested to provide a legitimate basis for the researcher to access patients records/case notes to extract identifiers, including name, NHS number and date of birth, and match them with radiology reports and case outcome in terms of abuse or accident. This was a prospective study with a cohort size of 20 children/patients.

Following consideration of this application through the ECC fast track process (category four - 'applications where applicants are only accessing data on site to extract an anonymised/ effectively pseudonymised dataset') the Committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State for Health.

Amendments

PIAG 4-08(d)/2003 National Confidential Inquiry into Suicide and Homicide (NCISH)

The study within the Inquiry had been commissioned by the Healthcare Quality Improvement Partnership (HQIP) to carry out an in-depth study examining the quality of risk assessment in people with mental illness through retrospective case note review of 100 cases of suicide and homicide. These cases would be randomly drawn from the Inquiry's database and on the basis of items already completed in the core Inquiry questionnaire.

Considered by Chair's action, it was noted that no additional information other than that already processed under the Inquiry's current support would be collected for this pilot study. Patient's case notes would be requested for the 12 months preceding the fatal incident (homicide/suicide). The original case notes would be returned to the relevant NHS Trust within 8 weeks of receipt and its copies shredded after use (also within 8 weeks). Identifiable data for this pilot study would not be retained by the Inquiry and the results of the study would be published in anonymised format.

It was also noted that the data for this pilot study would be processed under the Inquiry's original security arrangements stated in its system level security policy and in compliance with the provisions and principles of the Data Protection Act 1998.

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health for this pilot study, subject to the specific condition that feedback would be provided on the outcomes of this pilot study once complete (September 2013).

Update on previous applications

ECC 3-04 (R)/2011 National Diabetes Audit (adult)

The contract for the National Diabetes Audits had been awarded to the NHS Information Centre as prime contractor in June 2011. Since that time contract negotiations with Diabetes UK and the Yorkshire and Humber Public Health Observatory (YHPHO) had commenced and remained ongoing. Diabetes UK had

as yet been unable to appoint a GP Clinical lead, but interviews had been undertaken in readiness of contracts being awarded. In the meantime meetings were continuing between the NHS Information Centre and Diabetes UK.

ECC 7-04 (a)/2010 Research Capability Programme – end closure report

It was confirmed that the applicant would submit a formal end closure report of the pilot for the March 2012 meeting. The applicant had updated on the current operational position and stated that the development and delivery of data to Study Owners had been completed and no further operational data processing was planned. They would still respond to subject access requests as they arose which would involve further data processing so as to meet legal obligations. The applicant had re-confirmed that they would be transitioning to the Medicines and Healthcare products Regulatory Agency (MHRA) in due course and would keep the Committee fully updated on progress.

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

This application from the University of Manchester had been considered at the September 2011 Committee meeting. The Committee had been supportive of the application in principle and recognised that there was no practicable alternative to the methodology suggested. Members asked how reasonable efforts would be made to inform patients. The applicant's response asserted the difficulties in informing the cohort of the sensitive nature of the study; in particular it was noted that informing a cohort with schizophrenia of a study into homicide would be potentially very distressing and harmful for the cohort themselves. The applicant confirmed that clinical and demographic data would be separated and stored separately for six years and that the one researcher would have had prior access to the NCISH data for the purposes of the original NCISH application. The responses were sent to original reviewers and it was agreed that minimum criteria under the Regulations appeared to have been met, and a recommendation of provisional support would be provided to the Secretary of State for Health.

ECC 8-05(f)/2010 - A National Neonatal Research Database

This application proposed to set up a national neonatal research database to be used as a research resource. A recommendation of support was sought to enable routinely collected patient identifiable data to be populated on this research database. In addition to routinely collected clinical data, the application also included requested use of NHS Number, hospital ID, date of birth, date of death, postcode, gender, ethnicity, maternal NHS number and ethnicity, and postcode of infant at two years old.

Following consideration of this application at the Committee meeting in December 2010, the Committee had agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State for Health, subject to clarification and specific conditions of support. The applicant submitted satisfactory responses to these, therefore final support had been provided.

3. For consideration items

3a. NHS Information Centre – Hospital Episode Statistics transition paper

The Committee noted that the NHS Information Centre (NHS IC) was currently in receipt of support with respect to the Hospital Episode Statistics service. It was suggested that this might no longer be required following passage of the Health and Social Care Bill as this legislation might include, in its final form, provision for the NHS IC to gain its own powers to process personal identifiable information. However, the NHS IC's contract with its current data hosting provider Northgate was ending, thus a transition plan was required until new powers, if any, were acquired.

This item was originally discussed by the Committee in 2011, and was also presented to the National Information Governance Board. Previous discussions indicated that the transition would affect the current infrastructure to support the processing of HES data, but not change the purposes or the extent of patient identifiable data currently supported. However, a change to the current support had been

indicated through extending the current retention arrangements of the source data once linkages had been carried out in relation to customer requests.

As a whole, the Committee supported the need to carry out a detailed set of transition activities in order to enable the NHS Information Centre to prepare for its enhanced responsibilities in the future. It agreed that the approach appeared sensible and was taking place in a managed environment. Based upon this paper, members agreed that there was no requirement to provide updates to the Committee at regular intervals; however, they requested to receive an update before Phase 2 commenced. It was appreciated that due to the proposed timescales Phase 2 would commence after the formal abolition of the NIGB. As the status of advice and approvals under the Regulations at that time was currently unknown, members therefore requested that a formal report against progress be provided to the Committee either in January or February 2013.

Members noted that a rolling three-month retention period would be assigned to source datasets following previous communications around retention periods. If aspects of the source data would be required to fulfil a customer request then the review period would begin again from that point. As a whole, members were supportive of this approach and agreed that repeated upload of duplicate datasets would be inefficient, and this approach represented a pragmatic compromise to support the activity. However, while supportive in principle of the approach, members queried how often this situation had occurred, for example, how often over a 6-month period did a subsequent customer request determine that the same source data should be re-loaded? Members sought clarity on this issue so as to provide evidenced justification to support this change in retention arrangements under the current terms of support.

Members also noted that there should be continuing communication between the NIGB office and the NHS IC in relation to this transition activity so as to provide support as necessary; if significant issues arose they could also be escalated to the Committee as necessary.

3b. NHS Information Centre (NHS IC) – National Cancer Audit applications

ECC 1-03(c)/2012 The National Head and Neck Cancer Audit
ECC 1-03(d)/2012 The National Bowel Cancer Audit
ECC 1-03(e)/2012 The National Lung Cancer Audit

These applications detailed three cancer audits which process confidential patient information under the support provided to the NCASP application (ECC 1-06(c)/2009) including name, address, date of birth and NHS number with the aim to address the following; *"Are patients receiving appropriate primary treatment (including adjuvant therapy) from appropriate specialist teams".* These applications were provided in response to the outcome from the September 2010 Committee meeting, where the Committee had requested that for audits where NHS Number was almost or fully complete, the submission of individual applications should set out details of the identifiers required and how these could be reduced in identifiability so that a pseudonymisation approach could be pursued as an exit strategy from reliance upon these Regulations. These could be submitted on an incremental basis, preferably in suites.

In addition, after an interim report had been considered at the July 2011 meeting, the Committee had requested that the individual applications include confirmation of the NHS IC's involvement in the distribution of local patient information leaflets, including how widely these were distributed, how they were distributed at a local level and what the NHS IC specifically were undertaking to encourage this distribution. The Committee had recommended significant movement towards reducing the collection and retention of identifiable data items by the NHS IC, in particular the continued requirement of patient name and postcode in order to achieve an appropriate exit strategy under these Regulations. The Committee also requested that the applicant investigate the proposed alternative that NHS number should be validated automatically at a local level when the submission to the NHS IC was made, for example by using the Personal Demographics Service.

The Committee were of the view that this would negate the need for patient name and full justification should be provided for the Committee's review if the requirement were to continue.

Members were pleased to note that patient information leaflets were provided by the NHS IC and that trust contacts were made aware of these. Members were mindful that the obligation to make reasonable efforts to inform patients of the uses of their data was a requirement under the Data Protection Act 1998 (DPA). It was reiterated that as the NHS IC had a key role to play in national clinical audit, this should be reflected in the commitment to inform patients. Members noted that whilst trust contacts were made aware, there was no information to reflect to what level leaflets were distributed at a local level. Members agreed that it was therefore difficult to determine whether patients were sufficiently informed that the data collection was taking place. Members suggested that the NHS IC request feedback from trust contacts at regular intervals regarding the dissemination of leaflets and requested further information regarding how widely these were distributed and the NHS IC role in encouraging this. In addition, members suggested that the NHS IC explore other options to inform patients, for example by making patient information leaflets available on patient websites such as NHS Choices, or including information on national clinical audit in appointment letters. As informing patients of the uses of data was a requirement under the Data Protection Act 1998 (DPA), it was recommended that the Information Commissioner's Office could be contacted to ensure that appropriate and reasonable efforts to provide fair processing information were being made in line with DPA requirements.

In reviewing the responses around reducing the collection and retention of confidential patient information, members noted that each audit had distinct requirements for the processing of confidential patient information. Concerns were raised that whilst the National Bowel Cancer audit and the National Lung Cancer audit did not specify that they collected patient name, the National Head and Neck Cancer Audit included this as a data item collected by the NHS IC. It was discussed that name appeared to be used at a local level to identify a patient by those providing care and treatment for the patient, but it was not clear whether this was then submitted to the NHS IC and for what purpose. Members agreed that clarification should be provided by the next meeting in March in relation to the approach outlined within the Head and Neck cancer audit, in particular whether name would be accessed by the NHS IC and, if so, why this was necessary.

In reviewing responses around validating NHS number, Members noted that the Bowel and the Lung Cancer audits detailed the validation of NHS number upon submission of data and that MRIS would be used to validate NHS number in the Head and Neck audit. Members queried whether an investigation into the validity of NHS numbers submitted had been carried out and requested further details in relation to this.

NIGB Office update: further information in relation to the use of name and validation of NHS number was received by the NIGB office following the committee meeting. It was confirmed that name was required for all audits and validation of NHS number could not be carried out at a local level upon submission, therefore there had been errors in the information presented to the Committee. To ensure that members would be given opportunity to consider the updated information in full, the applicant was asked to submit a formal response clarifying the arrangements regarding the processing of name for all three audits, including validation processes and retention of name following validation.

Members additionally queried how dissent would be recorded within the system used to collect audit data. It was noted that as a number of agencies would be inputting data the system would need to identify to all of these that a patient had dissented once to the use of their data for audit purposes. Members agreed that further information regarding the management of dissent should be provided in time for the September 2012 Committee meeting.

The Committee noted the assertion that the proposed Health and Social Care Bill, due to come into effect by April 2013, would provide a long term exit strategy to the NHS IC's dependence on support under the Regulations. In order to aid clarity on this point, members requested further details in relation to the powers that the Bill would provide the NHS IC to collect data for audit purposes.

In conclusion, members advised that the applicant should consider how to best monitor the dissemination of patient information leaflets and different approaches to informing patients, ascertain validity of NHS number submitted at a local level and consider how dissent would be recorded within the system on an ongoing basis. It was requested that an update be provided for the September 2012 committee meeting. Following the NIGB Office update, a formal response would be presented to the March 2012 meeting to discuss the issue of patient name inclusion within the audits. In line with this, members agreed to recommend continued support for the use of NHS number, date of birth, date of death and postcode within the three submitted applications; but name was currently excluded.

3c. Cancer Registries annual review of specific support

The United Kingdom Association of Cancer Registries (UKACR) has specific support under the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information for medical purposes related to the diagnosis or treatment of neoplasia.

The review documentation provided information relating to the modernisation of data processing through the English National Cancer Online Registration Environment (ENCORE), the continued requirement for collection of confidential patient information, information governance within the cancer registries and planned activities for 2012. An appendix was provided which detailed all releases of confidential patient information by the cancer registries between May 2010 and April 2011.

Members considered the information provided as part of the annual review. It was noted that the modernisation of data processing by the use of the ENCORE system would bring substantial benefits to the work and information governance of the cancer registries. Members noted the information provided in relation to errors that had occurred when a third party had used address data held by the registries to distribute surveys. It was noted that this had been appropriately escalated to the Information Commissioner and that controls had been put in place to ensure third parties were not provided with address from cancer registries for the purposes of contacting patients.

Members agreed to recommend that the specific support provided should continue for a further year.

4. Resubmissions

4a. ECC 8-06(g)/2011 A retrospective cohort mortality of workers in Great Britain 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 recruited by the Health and Safety Executive (HSE) between 1975 and early 1980s. A recommendation for class 4 and 6 support was requested to access mortality data (date and cause of death) from the Medical Research Information Service (MRIS). Access was requested to date and cause of death from MRIS for those patients recruited into the original study by the HSE.

This application was considered at the December 2011 meeting where Members agreed that support could be given to provide mortality data from MRIS. However Members agreed that if flagging for mortality was to continue they would require further information regarding why those who were alive could not be informed, whether there was a control arm to the study, why a ten year retention period was specified and further information regarding patient involvement. Requests for clarification regarding a control arm and patient involvement were made accordingly.

The recommendation of support was provided to allow tracing of the cohort via MRIS and collating mortality data for those who had died. If MRIS data were to be obtained prospectively the Committee were of the view that the living cohort should be informed of the uses of their data. Members suggested that contact details could be provided by the Personal Demographics Service and asked the applicant to provide further information in relation to the feasibility of contacting the living cohort to inform them of the uses of their data.

The applicant provided a resubmitted application to the February 2012 meeting responding to the issues identified by the Committee. The applicant confirmed that the study would flag the cohort for mortality on a prospective basis. It was confirmed that contacting the cohort through GPs using MRIS, in line with the suggested condition of support, might cost upwards of £15,000, depending on the number of individuals that were found to be alive. In addition the distribution of information would provide an additional burden on GP practices. It was confirmed that the study would compare mortality rates of cohort with that of the general population and higher exposure cases compared with lower exposure cases. Retaining the data for ten years would allow the examination of the data for presence of long-latency effects, which the applicant asserted would lead to a more comprehensive characterisation of the health experience of the cohort. In addition it would ensure that the data would be available for any international pooled studies. Details of plans to consult with an independent scientific advisory committee, Working Group on Action to Control Chemicals (WATCH), were included within the resubmission. Members of the group included representatives from industry and trade unions as well as independent academics.

Members considered whether the cost of £15,000 and burden on GP practices was proportionate given the limited confidential patient information that the applicant would receive from MRIS. Members agreed that the cost might be considered reasonable. However discussion focused on the burden that contacting the cohort this way would put on GPs and the likeliness of engaging GPs for this reason. Members agreed that it was unlikely that the applicant would be successful in contacting the cohort through GPs and could not identify any other possible route for informing each individual by post, noting that employers were not likely to hold current addresses for individuals. In line with this Members agreed that it was particularly difficult to contact individual members of the cohort. Members noted that the cohort had consented to take part in the original study and agreed that in these circumstances, taking into account the public interest in the activity, it would not be proportionate to require that the applicant write to each individual to inform them.

Members noted the applicant's confirmation regarding the control arm of the cohort and the ten year retention period. Whilst Members agreed that it would be difficult to inform each individual, they were mindful that the fair processing requirement of the first principle of the Data Protection Act 1998 would still need to be satisfied and reasonable efforts to inform the cohort should be made. In line with this they discussed the attempts that would be made by the applicant to inform cohort members. It was noted that WATCH, an independent scientific advisory committee, would be consulted and the Committee queried whether the trade union members of that committee would be able to inform their members that the study was occurring. In addition, Members advised that a notice detailing the study should be placed on relevant websites to ensure that reasonable efforts were made to inform the cohort.

Members agreed that informing individual members of the cohort would not be practicable given the burden that this would present to GP practices. In line with this it was recommended that the conditions of support be amended to comprise a favourable opinion letter from a Research Ethics Committee, confirmation of a satisfactory security review, and demonstrable reasonable effort to inform the cohort of the uses of their data, including disseminating information via trade unions and appropriate websites. The Committee agreed to recommend to the Secretary of State that he approve support for this application subject to the above conditions.

4b. ECC 8-05(h)/2011 A study of MRSA Carriage and Infection in the United Kingdom

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 United Kingdom. The secondary objectives of the study were to use bacterial sequence data to determine MRSA transmission pathways within and between hospitals in the United Kingdom, 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 4 and 6 support was requested for researchers to access confidential patient information without prior consent in order to extract data 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.

Access to Addenbrooke's hospital records was requested in order to extract patient data, including date of birth and postcode, for analysis. In addition, for the national aspect of the study, access was requested to information, including date of birth, from the organisations listed above.

This application had been considered at the December 2011 meeting where Members agreed to recommend support for the regional/national aspect of the study. However Members considered that the applicant had provided insufficient evidence that consent could not be obtained to carry out a case note review for those patients treated at Addenbrooke's Hospital. In line with this the Committee advised that consent should be sought from those patients within Addenbrooke's Hospital and requested clarification regarding how patients within the hospital would be informed that the study was taking place and the outcomes of the consultation with patients and members of the public. A resubmission was made to the February 2012 meeting in which the issues identified by Members were addressed by the applicant.

The applicant confirmed that details (initials, hospital number and date of birth) relating to all patients would be required from the infection control database for tracking purposes to ensure that de-duplication could take place between the Addenbrooke's Hospital data and the national aspect of the study. In addition, the applicant asserted that seeking consent for the case note review aspect of the study would have implications for data integrity and analysis and that consent would not be feasible for a number of patients, e.g. those who had died. Further clarification was provided that three members of the study team would have legitimate access to data on the infection control database and in patient's notes as part of their role providing clinical care within the hospital. Access was therefore requested for one research nurse only.

The applicant asserted that publicising the study within Addenbrooke's Hospital might adversely affect patient participation. Details of the consultation with Addenbrooke's Patient Panel were provided and Members informed that they raised no concerns regarding the use of identifiable patient data without consent.

Members noted the assertion that 100% ascertainment was required for the tracking arm of the study and the assertion that informing patients would adversely affect the results of the study if patients were to decline consent. However, Members were mindful that there was opportunity to inform patients that the study was taking place and reiterated that support could not be inconsistent with the requirement of the first principle of the Data Protection Act 1998 (DPA), to make reasonable effort to inform data subjects of the uses of their data. In line with this Members agreed that efforts should be made to inform patients that the study was taking place and to respect any dissent, although it was considered that the number of individuals dissenting was likely to be low. Members suggested that this could be achieved by putting up posters within hospital wards.

Members discussed whether consent could be obtained in order to review the case notes of those patients who were found to be MRSA positive. Members noted that support would be required for one research nurse only in order to access case notes. It was noted that the research nurse would have the

equivalent duty of confidentiality as a member of the patient's clinical care team. However, Members were not convinced that patients should not be informed of the study because they might decline consent. Members agreed that it would be reasonable to inform patients that the study was taking place using a similar model to that detailed for the tracking phase of the study, allowing dissent where it was indicated. Members noted the outcome of the public consultation regarding the study.

Members agreed that explicit consent would not be feasible for the study. However Members agreed that reasonable efforts should be made to inform patients that the study was taking place, in line with the requirement of the Data Protection Act, and suggested that the applicant ensure that posters were displayed in hospital wards. Where dissent from an individual was recorded, this should be respected. If levels of dissent made the study impracticable, evidence of this should be submitted to the Committee as soon as possible.

The Committee agreed to recommend to the Secretary of State that he approve the application subject to confirmation of a favourable opinion from a Research Ethics Committee taking into account the updated patient information, confirmation of satisfactory security arrangements, and demonstration of reasonable efforts to inform patients that the study was taking place. Members suggested that posters could be displayed within hospital wards informing patients of the study, and emphasised that any dissent from patients resulting from the posters should be respected.

5. New applications

5a. ECC 1-05(a)/2012 End of Life care Repository

This application from the South West Public Health Observatory (SWPHO) and sponsored by the National End of Life Care Intelligence Network (NEoLCIN), detailed the establishment of a national end of life care data repository with an aim to increase knowledge and understanding of end of life care and provide information to commissioners, service providers and the public. Class 4, 5 and 6 support was requested in order to access linked Hospital Episode Statistics (HES) and ONS primary care mortality database (ONS PCMD) data and data on all patients in ONS PCMD on a fortnightly basis. Data would include postcode, NHS number and date of death and contain all those patients who had died in England from 2001 onwards.

The application had previously been considered at the December 2011 meeting, following which the application was withdrawn. Members noted that the current application had been considerably amended in comparison to the previous version. Members recognised the potential public interest in the establishment of the database and were supportive of the overall aims as outlined within the application.

As Members agreed that they were supportive of the application as a whole discussion focused on the extent of identifiable data items requested.

Postcode was requested in order to link to ONS Communal Establishment data and establish Lower Super Output Area (LSOA). Members queried whether it would be possible for the NHS Information Centre (NHS IC) to provide a linked dataset which included HES, ONS PCMD, ONS Communal Establishment data and LSOA. It was understood that the NHS IC had prior access to these datasets for their own purposes. In addition, Members were of the view that the NHS IC already provided a service whereby bespoke classifications/reference tables could be linked to patient records by postcode and returned to the applicant without the need to disclose the postcode itself. It was agreed that this option should be explored further.

NHS number was requested to allow linkage of the HES and ONS PCMD on a fortnightly basis. Members noted the assertion that a separate ONS PCMD extract had been requested in order to allow data for those patients not recorded on HES to be included in the database. Members were of the view that it might be possible for the NHS IC to provide data on all patients within the ONS PCMD and for HES data to be linked to those where a match existed. Members queried whether this would negate the need for NHS number for this linkage purpose.

Members recognised that NHS number would also be required for future linkages which would help achieve the overall aims of the application. In line with this Members queried whether it would be possible for the NHS IC to provide NHS numbers which were pseudonymised using an algorithm that could be repeated when further linkages were required.

Members noted that the patient's general practitioner was considered a sensitive item on the HES dataset, and further that virtually all practices now operated as a partnership and many patients were not cared for by their registered GP but by doctors within the practice. Members asked if registered general practice and/or the pseudonymised general practitioner code would be sufficient for the stated aim.

Members agreed that date of death would be an important data item for analysis purposes.

Members were of the view that if the alternatives detailed above could be utilised, the extent of identifiable data required by the applicant would be reduced significantly. Members noted that support under the Regulations cannot be inconsistent with the principles of the Data Protection Act 1998 and that the third principle specifies that information must be adequate, relevant and not excessive. It was therefore recommended that the applicant explore these alternatives in detail. The Committee suggested that it would be beneficial for a meeting to take place between the NHS IC, the applicant and a sub-group of ECC Members in order to determine which of the proposals outlined above would be feasible and which would require support to allow disclosure to the applicant.

The fifth principle of the Data Protection Act specifies that personal data should not be kept for any longer than is necessary for the purposes specified. With this in mind Members considered the retention period for identifiable data specified within the application and noted that the application stated that retention periods would be directly linked to the needs and requirements of the group. Members requested further details about how often the requirement to retain patient identifiable data would be reviewed.

Members agreed to recommend to the Secretary of State that he approve this application, subject to confirmation of how often the need to retain patient identifiable data would be reviewed and clarification regarding the feasibility of the NHS IC carrying out the following activities on behalf of the applicant:

a. Provision of data for <u>all patients</u> recorded on the ONS PCMD (within the specified time frame) linked to the ONS Communal Establishment data and ONS LSOA data and, for those patients admitted to hospital prior to their death, provision of HES data linked to the ONS PCMD.

b. Provision of a pseudonymised NHS number within the dataset, using a method that, if required in future, could be repeated to allow future linkage to other data.

5b. ECC 1-05(b)/2012 Record Linkage in the ALSPAC

This application from the University of Bristol detailed the linkage of information relating to the health, education, benefits and earning and criminal convictions for the Avon Longitudinal Study of Parents and Children (ALSPAC) cohort (around 14000 individuals) who had previously consented to inclusion into the original study. A request for class 1, 4 and 6 support was made to enable the extraction of confidential patient information without consent from a number of sources, including primary care data held by general practices; Hospital Episode Statistics (HES); NHS Central Register; and NHS patient demographic data from the NHS Information Centre (NHS IC). NHS number, date of birth and GP registration were requested to allow the linkage of data using services provided by the NHS Information Centre (NHS IC) and NHS Wales Informatics Service (NWIS). Only pseudonymised data which included a unique reference number (ALPSAC ID) for each individual would be available to the applicant.

The Committee noted that the ALSPAC cohort were a particularly important group in terms of research that could be carried out using data collected about them. As a whole, the Committee agreed that it was important that the potential use of data from the ALSPAC cohort were maximised and, in line with this, were supportive in principle of the aims of the application.

Members noted that demographic data would be provided to NWIS, who would pseudonymise and link to clinical data using methods within the Secure Anonymised Infrastructure for Linkage (SAIL). Members were pleased to note that this provided a secure framework which ensured that data was fully pseudonymised and meant that no individual would require access to both demographic and clinical data. In addition, Members requested further information regarding how benefit, employment, education and criminal records would be linked with health data.

Members discussed the information sheets and consent form provided. Members raised concerns that these did not explicitly inform the cohort of the consequences of not responding, i.e. that if they did not reply their data would be linked and included in the study. Members agreed that it was crucial to ensure that the cohort were fully informed of the consequences of not responding, particularly if non response was considered not to be dissent. This information should be placed in a prominent position within the patient information materials. In addition, Members queried how an individual could opt out of being included within the ALSPAC cohort and how and when they would be informed that this was possible.

Members agreed that the patient information leaflet and consent form should be amended in line with the comments above and that the remainder of the cohort (6500), who had not yet been contacted, should be written to using the outlined approach. Members were of the view that once this amendment had been made it should be sufficiently clear that non-response would mean that data would be used and, taking into account the secure data linkage methods proposed, agreed to recommend support for the remaining cohort.

Members noted attempts that had been made to obtain consent from a sub-cohort of 2000 randomly selected participants to form a pilot in order to inform the request for support. It was noted that 41% had responded and of these 93% had agreed to the linkage of their data. Following this, a further 5500 participants were contacted and similar response and consent rates were found. However, in line with the comments above, Members were concerned that those already contacted might not have been provided with sufficient information to allow them to make an informed decision whether to respond or not. In these circumstances the Committee agreed that the non responders within the pilot could in fact be dissenting from the use of their data as they had not been fully informed of the consequences if no response was received.

As Members were concerned that these 7500 individuals had been unable to make an informed choice whether to respond or not, they agreed that they could not recommend support for this half of the cohort at this time. However, Members agreed that once the remaining cohort had been contacted, the response rates could be compared with that of the pilot cohort to determine whether there was an increase following the amendment to patient information materials. Members agreed that an increase in responses would suggest that non-responders within the pilot cohort may have been showing passive dissent.

Members noted that access to the entire GP record was requested. Members were concerned that the GP record might contain particularly sensitive data and information about third parties. Members agreed that free text and particularly sensitive information such as that relating to sexual health or termination of pregnancy should not be provided to the applicant.

The Committee requested that the applicant clarify how additional datasets including benefit, employment, education and criminal data would be linked to health data; clarify how individuals would be able to dissent from further inclusion in the ALSPAC cohort and how they would be informed of this right on an ongoing basis; amend patient information sheets and consent forms to ensure that the cohort were fully informed that non-response would result in their data being used in the ALSPAC study; ensure that free text and sensitive data fields, such as those relating to sexual health or termination of pregnancy, were not extracted unless explicit consent had been provided; satisfy security concerns in liaison with the Department of Health security review team; and provide a favourable Research Ethics Committee opinion covering any changes made as a result of the above requests. The original reviewers of the application would then determine whether satisfactory assurances had been provided to allow a recommendation to the Secretary of State to be made.

5c. ECC 1-05(c)/2012 Millennium Cohort Study Fifth Sweep

This application from the University of London detailed the next stage of the UK Millennium Cohort Study. The multidisciplinary research project had followed the lives of over 19,000 children born in 2000/1, charting the effects of events and circumstances in early life on outcomes and achievements later on. Confidential patient information was requested to use the NHS Central Register data to provide address information for those participants (1350 individuals) for whom confirmed address was not held, in order to write to them to participate in the next stage of the study.

Members considered the consent form which had been provided by the applicant, in particular they noted the consent form titled *Permission to Obtain Health Information,* which contained the following information "*Getting the baby's NHS number with your permission, from these records would help us keep in touch with you"* and *"I give my permission for Child of the New Century to follow my baby's National Health Service registration where necessary". Member*s were of the view that the consent form provided sufficient information for the applicant to provide consent to access address data from the NHS Central Register data. Members noted that the 1,350 would have provided consent using this form.

Members advised that support was not required as consent was considered sufficient to access the information.

5d. ECC 1-05(d)/2012 The impact of FLT3 and NPM1 status in Acute Myeloid Leukaemia

This application from the Freeman Hospital detailed a research study into the effect of 2 molecular changes, FLT3 and NPM1, on the outcome of patients with Acute Myeloid Leukaemia (AML). Data for all patients from the Northeast diagnosed with AML from January 2007 to January 2011 (approximately 400 patients) would be collected. Information would be collected from the patient's hospital notes and from tests carried out on bone marrow samples at the Centre of Life, Institute of Genetic Medicine. Patients would be identified using lists of patients discussed at Haematology multidisciplinary meetings in Newcastle, Teeside and South of Tyne. Class 1, 4 and 6 support was requested to allow the identification of patients, the extraction of information from hospital notes and the linkage of hospital data with test results prior to anonymisation. This would be carried out by one researcher.

Members agreed that the study outcomes as a whole had a high public interest and that the application detailed important research. Members noted the retrospective nature of the study and that many of the patients would have died. It was discussed that if the applicant was asked to determine who had died, in order to seek consent from the living, it would be necessary to access more confidential patient information than required to carry out the research activity. Members also noted that the application stated that consent had originally been obtained for the use of bone marrow samples in research, although it was noted that a copy of this consent form had not been received. A view was raised that the number of patients detailed was not particularly large and the application did not specify how any cases of recorded consent would be managed.

On balance, the Committee agreed that consent would be difficult to obtain, noted that consent had been obtained for the use of bone marrow samples in research and that the researcher had worked as a specialist registrar in all hospitals involved and owed an equivalent duty of confidentiality to a health professional to patients. It was agreed that the benefits of the research were such that support could be recommended so that the research could be carried out without explicit consent, subject to further clarification over how dissent would be managed and what the bone marrow consent form included.

Members agreed to recommend to the Secretary of State that he approve this application, subject to clarification on how patient dissent on use of their data for research would be managed and provision of a copy of the bone marrow consent form referred to within the application.

5e. ECC 1-05(e)/2012 Investigation of genetic and environmental factors underlying cardiovascular disease – the London Life Sciences Population

This application from the University of Surrey detailed a cohort study of adults in North West London with the aim to determine the risk of cardiovascular disease in people of British Asian ethnicity. The outcomes of the study included making recommendations for the better management of patients within the group who appeared to have increased cardiovascular risk. A cohort of 26,000 had given consent to take place in the original cohort study and the application detailed the identification of a cohort of 100,000 control patients matched by age, gender and ethnicity. A recommendation for class 1, 4, 5 and 6 support was requested to allow access to coded GP practice information to allow configuration of a MIQUEST query to identify controls. Once controls had been identified, support was requested to allow linkage to Stroke Improvement National Audit Programme (SINAP), Myocardial Ischaemia National Audit Programme (MINAP) and Hospital Episode Statistics (HES) data held by the NHS Information Centre (NHS IC). Access to confidential patient information was requested to allow the identification and extraction of NHS number for a control cohort.

The Committee agreed that there was a clear public interest in the activity taking place and that they were supportive of the application in principle. The Committee considered whether there were any practicable alternatives to the disclosure of confidential patient information without consent. They noted that in some GP practices the applicant had stated that it would be possible for a member of staff to run the queries on behalf of the researcher, but that in others this would not be possible due to the level of technical knowledge required to carry out the extraction. The Committee agreed that it was not clear how complex the task would be and therefore could not ascertain that this was the case. In line with this they requested further information regarding why a member of GP practice staff at each site could not be trained to run the query on behalf of the researcher. In addition, Members agreed that they would require further information regarding the cost of the GP practice systems involved carrying out the automatic extraction and encryption of data, negating the requirement for identifiable information to be accessed by a researcher at each site.

Members noted the large control cohort that was specified and agreed that consent would not be feasible if controls of 100,000 were required. In addition Members noted that the LOLIPOP cohort had provided consent for the access to their information. Members sought reassurance that all of the 26,000 LOLIPOP cohort had agreed to the consent terms included within the application.

Members queried what information would be extracted from GP practice sites for the control cohort, noted that postcode would be used to determine index of deprivation and sought confirmation that the applicant was proposing to extract NHS number only. The Committee requested further clarification whether NHS number would be extracted from GP practice sites in the clear or whether this would be pseudonymised prior to disclosure. Members were of the view that if a consistent algorithm could be applied to NHS numbers within GP practices and NHS IC data this would allow linkages to take place using pseudonymised data only. Support would then only be required to allow access to patient data within GP practices, provided it was not possible for the GP staff to run queries on the applicant's behalf.

Members queried whether there would be any additional uses of NHS number. Section (i) of the application form stated that this would primarily be used for linkage and Members requested confirmation of any additional uses. If, following clarification from the applicant, it was confirmed that identifiable data was to be extracted from GP practices, Members requested further information as to why 100,000 controls were required and queried whether it would be possible to carry out the study using a smaller proportion of the cohort and a smaller number of controls.

The Committee requested that the applicant clarify why it would not be feasible to train a member of GP practice staff at each site to run the query on a researcher's behalf; confirm whether the costs of extracting the data automatically using the GP systems had been explored and why this option would not be feasible; confirm what identifiable data would be taken from GP sites in relation to the control cohort; confirm whether NHS numbers could be pseudonymised using a consistent algorithm in GP practice and NHS IC datasets to allow linkage to take place without extracting identifiable data from GP practices or

the NHS IC; confirm whether there were any further uses for NHS number, other than to carry out linkages; and, if identifiable data were to be extracted from GP practices, clarify why 100,000 controls were required and consider whether it would be possible to carry out the study using a smaller proportion of the cohort and a smaller number of controls. The original reviewers of the application would then determine whether satisfactory assurances had been provided to allow a recommendation to the Secretary of State to be made.

5f. ECC 1-05(f)/2012 The CAPE Study: Community care pathways at the end of life

This application from the Institute of Public Health, University of Cambridge set out a study to access patient identifiable information from GP and Community Nurse records of 400 recently deceased patients in order to summarise the care the patient received in the last year of life. Twenty GP practices would be recruited over two years, the first ten within Cambridgeshire PCT. The remaining practices would be recruited more widely across the East of England. The patient clinical information would be summarised and inform discussions with health professionals, social care professionals, carers, next of kin and potentially care home managers (if the patient lived at a care home before death) involved in the care of the patient in their final year. A recommendation for class one, two, four, five and six support was requested to collect patient identifiable information that is name, NHS Number, GP Registration and gender without consent and access patient medical records (GP and Community Nurse records).

Members agreed that the study would have beneficial outcomes and improving end of life care was important and very much in the public interest. Members noted that name and NHS number would be required in order to extract Community Nurse records from an NHS repository where some may have been sent for storage. Members noted that requests for the extraction of data from the NHS repository would be made from GP practices by the researcher. In addition date of death would be required in order to access the care given in terms of days before death. It was noted that only anonymised data would be extracted from GP practices.

Members noted that interviews would be carried out with members of the care team and next of kin. Members agreed that the researcher in this instance would owe a duty of confidentiality to the patients and queried how a researcher, who had had prior access to a patient's medical records, would ensure that no confidential information was then disclosed to the third parties being interviewed. Members requested further information on the safeguards that would be put in place to ensure that patient confidentiality was maintained.

Members noted that the applicant had requested to view patient records 12 months prior to their death. Members queried why this length of time had been specified and a view was raised that the researchers should only access data in relation to 6 months prior to a patient's death and only any chronic diagnoses and medication prescribed for the diagnoses prior to this.

The Committee agreed to recommend to the Secretary of State that he approve this application, subject to clarification on safeguards put in place to ensure that researchers interviewing third parties about a patient's care would not disclose any confidential patient information included within medical notes; confirmation whether medical notes dating back to six months prior to a patient's death and any information on chronic diagnoses prior to this would be sufficient for the purposes of the study; confirmation of a favourable opinion from a Research Ethics Committee; and confirmation of a satisfactory security review covering all GP practice premises involved, including implementation of controls over access to records to ensure that only the minimum and necessary information would be accessed, use of appropriate antivirus precautions and encryption, clarification on whether the researcher would be left unsupervised, and confirmation that each GP practice's Caldicott Guardian had ensured a secure system would be in place at all times to support the above concerns.

5g. ECC 1-05(g)/2012 Understanding Hospital Admissions Close to the End of Life (ACE Study)

This application from the Institute of Public Health, University of Cambridge set out a study to access deceased patient identifiable information without consent. The researcher would like to identify 24

patients who were 65 years old and above and died at two hospitals (48 patients in total) in Cambridgeshire with the assistance of the bereavement service at each hospital. The deceased patients' record would be accessed by the researcher in order to identify health and social care professionals who treated the deceased patient in their final hours and to collect patient identifiable information which would inform qualitative interviews with these professionals and carers/next of kin about the care provided to the patient and whether or not admission to hospital was appropriate given the patient's circumstances (end of life). A recommendation for classes one, two, four, five and six support was requested to access patients' hospital records and collect patient identifiable information that is name, GP Registration, date of birth, date of death, full address (including post code), gender, ethnicity, place of death and condition.

Members agreed that the study would have beneficial outcomes and improving end of life care was important and very much in the public interest. Members noted that confidential patient information would be required in order to identify the care pathway of the patient and to identify the patient in interviews with the care providers and next of kin. It was noted that the application confirmed within one question that analysis would be carried out using anonymised data, but that identifiers were listed as being required for analysis in question 38 of the IRAS form including name, date of birth, date of death and other geographical identifiers which were not specified. Members queried why these identifiers, particularly name, were required for analysis purposes.

Members noted that interviews would be carried out with members of the care team and next of kin. Members noted that the researcher in this instance would owe a duty of confidentiality to the patients and queried how a researcher, who had had prior access to a patient's medical records, would ensure that no confidential information was then disclosed to the third parties being interviewed. In addition, Members were concerned that third parties who had provided clinical care for individuals may disclose further clinical details within interviews. Members requested clarification regarding what would be discussed in interviews with clinical care teams and further information on the safeguards that would be put in place to ensure that patient confidentiality was maintained.

Members noted that the study aimed to understand admissions to acute hospitals at the end of a patient's life and to identify what might have been done in order to prevent them. Members queried how the applicant would deal with any evidence of poor practice and how they would inform those who they carried out interviews of their rights and the risks for them.

The Committee agreed to recommend to the Secretary of State that he approve this application, subject to clarification as to why the specified identifiable data items within question 38 of the IRAS form were required for analysis purposes and how long these would be retained; clarification on safeguards put in place to ensure that researchers interviewing third parties about a patient's care would not disclose any confidential patient information included within medical notes; and clarification of the applicant's approach to dealing with any evidence of poor practice, including advising professionals being interviewed concerning their rights and related risks..

5h. ECC 1-05(h)/2012 FARSITE Recruitment

This application was from North West e-Health, a not for profit collaboration between the University of Manchester, Salford Royal Foundation Trust and Salford Primary Care Trust, and detailed the establishment of a search and retrieval tool for the identification, selection and invitation for recruits into clinical research (FARSITE). The tool would limit the amount of information displayed to researchers and allow GPs to decide whether their patient should be contacted for invitation to participate in clinical research. Class 2 and 6 support was requested to provide a legitimate basis for two technicians, employed by Salford Royal Foundation Trust, to access confidential patient information including name, date of birth, postcode and NHS number, in order to maintain the FARSITE system.

As a whole, the Committee agreed that they were strongly supportive in principle of the aims of the application and recognised that ensuring sufficient recruitment into clinical trials was a policy directive, provided a significant public interest and was to be commended.

Members noted that North West e-Health (NWeH) was specified as the applicant. As a data controller/processor must be a "person" recognised in law, and as it appeared that NWeH was not a legal entity, Members sought further clarification on the role of NWeH regarding whether they were a data controller or a data processor for the purposes specified within the application. Following on from this, Members queried whether the University of Manchester, Salford Royal Foundation Trust and Salford Primary Care Trust were acting as joint data controllers or data controllers in common. The term joint data controllers refers to situations where two or more bodies act together to determine the purpose of processing and data controllers in common applies where two data controllers share personal data for different purposes and process data independently of each other.

As GPs are data controllers for personal data generated within their practices, which FARSITE would receive, it was suggested that once the precise legal status of NWeH was resolved, an appropriate legal entity, such as one of the collaborators of NWeH, could reasonably enter into a mutually agreed data processing contract with the GPs. Once this data processing contract was in place, the technicians would then have a legitimate basis to access the data to maintain the FARSITE system as they would be acting on behalf of the GP, and would therefore not require support in order to carry out the activity.

The Committee highlighted that applications under the Regulations could only be approved where there was no other practicable alternative. On the basis that there appeared to be a practicable alternative, through management of this issue at a local level via standard data controller and processor contractual and data sharing agreements, the Committee were currently unable to advise recommending support for technician access to systems. It was strongly advised that the appropriate data controller and processor responsibilities should be established once participating GP practices were identified, and discussions should then commence with the relevant parties in order to establish these agreements.

Having considered the options for providing a legitimate basis for technicians to access the system for administration purposes, which was the main purpose of the application, Members noted that the application proposed to extract confidential patient information onto the FARSITE server for those patients with diabetes. The Committee raised general concerns that a new database of those patients within the selected GP practices with diabetes would be created and were of the view that it was therefore particularly important to clarify who would act as data controller for the established database.

Members were pleased to note that Read codes would be used to ensure that those patients who had dissented from the use of their information for secondary purposes would be excluded from the FARSITE system. However, Members queried how patients within GP practices would be informed that their data could potentially be used for this particular purpose in order to allow them to register their dissent for this use, and to ensure fair processing requirements under the Data Protection Act 1998 were met. An example would be informing patients that practices participate in clinical trial recruitment by sending out letters or displaying posters within participating GP practices.

Due to the number of queries that the Committee had regarding the data controller arrangements of the application, the Committee could not recommend support at this time.

6. Any other business

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

7. Upcoming meeting dates

27 and 28 March 2012