**Ethics and Confidentiality Committee (ECC) Meeting – Wednesday 19 September 2012**

*Members:*

Dr Andrew Harris (Chair), Dr Mark Taylor, Dr Patrick Coyle, Dr Tricia Cresswell, Ms Alison Emslie, Dr Colin Harper, Mr Stephen Hinde, Ms Gillian Wells, Mr Chris Wiltsher and Mr Terence Wiseman.

*In attendance:*

Dr Alan Doyle *(Director, NIGB)*, Ms Natasha Dunkley *(Approvals Manager, NIGB),* Ms Claire Edgeworth *(Deputy Approvals Manager, NIGB),* Mr David Evans *(Information Commissioner's Office, observing),* Mr Martin Frowd *(Senior Business Support Officer, NIGB),* Mr David Knight (*Department of Health),* Ms Clare Sanderson *(Executive Director of Information Governance, Health and Social Care Information Centre* - items 3a and 5a), and Mr Timothy Williams *(Clinical Practice Research Datalink, MHRA* - item 5a).

**1. Welcome and apologies**

Apologies were received from: Mrs Pauline Brown, Dr Tony Calland, Dr Robert Carr, Dr Fiona Douglas, Professor Julia Hippisley-Cox and Professor Jane Kaye.

**2. Declarations of Interest**

Dr Tricia Cresswell declared an interest in relation to item 3b and left the room for the duration of that item. Dr Cresswell also declared that she had met the applicant for item 5i, but the last contact had taken place more than ten years ago, so she remained present for the duration of that item.

**2a. Minutes of last meeting & matters arising**

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

An action arising from withdrawn application reference 4-03 (a)/2012 in July 2012 was for the office to liaise with the relevant DH team to seek clarification on the legal process for access to CMO data and to seek changes to the published procedure, as it had been identified that there would be no requirement to seek support under the Regulations if the disclosure was arising from the CMO. Ms Edgeworth reported that a letter had been sent from the office to the relevant DH team requesting that the published DH procedure document be amended. A response had not been received at the time of the meeting.

A further action was to identify what would be the remit of the Committee if there was a security breach in the context of an approved application. It was agreed that while it would be the responsibility of the data controller to manage, and the Information Commissioner's Office where appropriate, the Committee should be informed of any such breaches. Ms Dunkley provided an update that the standard conditions of support had been updated to include the requirement to notify the Committee via the office in the event of such a breach.

**2b. NIGB Office Report [ECC 2-03 (b)/2012]**

**For information**

Secretary of State (SofS) approval decisions

The Department of Health (DH) senior civil servant on behalf of the SofS had agreed with the advice provided by the Committee in relation to the July 2012 meeting applications.

IG Toolkit and SLSP submission

Following the action item from the July 2012 meeting, a small workgroup (Pauline Brown, Alison Emslie, Stephen Hinde and Chris Wiltsher) met to review the IG toolkit fields, with a view to identifying those key requirements of most importance to ECC consideration of applications, and to make recommendations. A verbal update was provided following apologies from the office that there had not been sufficient time to formally present the outcomes. The group had met and identified that many of the requirements were relevant, although the point was raised that the Committee's focus was in the specific data flows and management of security and confidentiality issues in the context of an application. Certain requirements were highlighted as being more of relevance to the Committee in the context of the application.

In the interim, Members were made aware that security assurance was now provided via IG toolkit submission with immediate effect. At time of writing, a more detailed process was being authored by the DH team with a view to publication on the website. Of importance to note was that the Toolkit typically reviews data controller arrangements; however for the purposes of the ECC (and DAAG) applications it had been agreed that where the data controller was effectively applying for a data processor to carry out the processing of confidential patient information, it would be the organisation physically processing the confidential patient information that would complete the IG Toolkit. Once the revised process was released, appropriate changes would be made to supporting documentation. Some issues had been experienced during this bedding-in period, and issues were being escalated to the DH IG Delivery team to ensure that applicants were supported throughout the process. In particular, as the IG Toolkit is not a mandatory requirement within Wales, it was reported that the DH team would be discussing this issue with Wales representatives to identify a satisfactory way forward.

**Fast Track applications**

**ECC 5-02 (FT1)/ 2012 Acute Inpatient Survey**

This service evaluation / patient survey application 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 2012 acute inpatient survey. 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 2012 (earlier for smaller trusts), who had had one overnight stay in hospital. In-patients 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. The application was considered at an office level as it was noted that this was a repeat of the 2011 acute inpatient survey and therefore fell within proportionate review criteria 14: *repeat projects.* A recommendation of support was requested to cover the transfer of patient identifiable information (as listed within the application) from trusts and the subsequent processing of this information by specified contractors. It was indicated that that NHS trusts would be advised to employ the service of one of the specified 'approved contractors' to reduce the cost, burden and risk in the provision of survey data. The applicant confirmed that the methodology and sampling frame were identical to those used for the 2011 acute inpatient survey. It was noted that GP practice code would be included within the data submitted from trusts for the 2012 acute inpatient survey and that the inclusion of this data item had been recommended by the ECC for previous surveys within the NHS survey programme. Following confirmation that the data flows remained unchanged from the 2011 survey, support was recommended for the repeated activity. This recommendation of support would be subject to the specific condition that it would not cover the transfer of patient identifiable information where a patient had indicated dissent.

**ECC 5-02 (FT2)/2012 Prognostic significance of incidental Troponin I rise in the elderly**

This research application from Norfolk and Norwich University Hospital detailed a request to access confidential patient information in order to carry out a study to investigate a raised troponin level with no identified cause in elderly patients and explore its effects on hospital readmissions and mortality. The study would compare a control group of patients without raised troponin and a group without a diagnosis of acute coronary syndrome. The study aimed to determine whether those patients with an incidentally

raised troponin have a worse prognosis compared with controls who have no raised troponin. This application was considered under fast track criteria 3, where applicants are accessing data on-site to extract anonymised or effectively pseudonymised data. Support was requested to allow access to admissions records at the medical assessment unit at Norfolk and Norwich University Hospital by the chief investigator in order to identify cases and controls. The hospital ICE system would be accessed to collect further information relating to troponin measurements and follow up patients at 1 month, 3 months, 6 months, 1 and 2 years. It was proposed that hospital number, date of birth and date of death would be collected to allow follow up to take place and age at event to be correctly calculated. Members noted the research would have public benefit by providing assistance to discharging physicians when concerning prognostic factors. Members had queried what means would be used to communicate the results to discharging physiciansMembers were pleased to note that posters would be displayed to inform patients that data collection was taking place, but queried whether posters would inform patients on how to opt out of having their data processed for these purposes.

It was noted that full date of birth was to be extracted and Members considered that in this instance it might be sufficient to collect month and year of birth only as the patients in question were 75 years of age and therefore it was not clear whether a margin of 30 days would be significant. In addition, Members noted that there was some inconsistency in the specified retention period and asked for confirmation of how long identifiable data would be retained. Members discussed the chief investigator's role and noted that he was an academic foundation doctor; Members requested confirmation that he was employed by Norfolk and Norwich University Hospital. Members noted that a consultant within the relevant department would be a member of the research team and advised that they would be responsible for supervising the chief investigator's access to and processing of patient data. Members agreed that they were supportive of the application as a whole and agreed to recommend support subject to satisfactory responses to some points of clarification. Satisfactory responses to these were received and the application was recommended for support subject to REC approval.

**ECC 5-02 (FT3)/2012 Radiotherapy Patient Experience Survey of NHS patients treated as patients in Radiotherapy Departments following up on the National Cancer Patient Experience Surveys 2010 and 2012**

This service evaluation application from the Department of Health and Quality Health detailed a radiotherapy patient experience survey. The survey would take place over 50 NHS trusts and include around 40,000 patients treated in spring 2012. Requested confidential patient information included name and address in order for Quality Health to write to patients with the patient questionnaire. It was detailed that no clinical data would be disclosed prior to consent and that Quality Health would only be aware that the patient had attended a radiotherapy appointment and DBS checks would be made prior to sending questionnaires. This application was processed under proportionate review criteria 1, applications to identify a cohort of patients to subsequently seek their consent. Members identified that the survey followed the same methodology used in previously approved applications where consent had been deemed as unfeasible and that security measures within Quality Health would remain identical to those applications. It was noted that, in line with previous applications, fair processing information would be provided at trust level and patients would be provided with the opportunity to opt out. Members agreed that they could recommend support for this survey activity, as consent was unfeasible and reasonable efforts would be made to inform the patient population.

**ECC 5-02(FT4)/2012 National Cancer Patient's Experience Survey 2012: Acute and specialist trust surveys of inpatients and day cases**

This service evaluation application from the Department of Health and Quality Health detailed a repeat of the National Cancer Patients' Experience Survey 2011. The survey required confidential patient information (name, address, sex, ethnic group, year of birth, ICD10 code, admission and discharge dates, speciality code, referring PCT, admission type and NHS number), to be sent to Quality Health in order to send out surveys to 120,000 cancer patients admitted between 1 August 2012 and 21 October 2012. The survey aimed to obtain feedback, inform commissioning, and provide the NHS Commissioning Board with an overview of cancer patient experience. Support was also required for mortality checks to be carried out by Quality Health using the Demographic Batch Service (DBS) prior to

sending out questionnaires. The application was considered at an office level as it was noted that this was a repeat of the 2011 National Cancer Patient's Experience survey and therefore fell within proportionate review criteria 14: *repeat projects.* It was confirmed that the purposes, methodology and data requested were identical to those detailed within the 2011 application. Following this confirmation, support was recommended for the repeated activity.

**ECC 5-02 (FT5)/2012 Small Bowel Cancer in Lynch Syndrome: A 20-year Single UK Centres Experience**

This research application from Central Manchester University Hospitals NHS Foundation Trust detailed a 20 year retrospective study that would improve current knowledge of the natural history of Lynch syndrome-related small bowel cancer. The study aims included development of a more informed assessment to identify risk factors and contribution to generating preventative, investigative and treatment protocols to manage patients at a high risk. The application was considered under proportionate review criteria 4; *Time limited access to undertake record linkage/validation and to pseudonymise the data.* Confidential patient information including name, date of birth and local hospital number would be accessed from the North West Cancer Intelligence Service in order to identify local patient notes at services across the North West and extract pseudonymised data relating to the history of the cancer. In addition identifiable data would be used to request tissue specimens from the Central Manchester University Hospital NHS Foundation Trust. The cohort would consist of around 75 patients and it was estimated that less than 10 patients would be alive. Members agreed that the research would be of public benefit and noted that minimal identifiers would be used to carry out linkage between datasets. It was queried whether consent could be obtained from living participants, however the applicant asserted that patients would be terminally ill and therefore it would be inappropriate to contact them in relation to the research. It was noted that the patients would need to be approached individually through GPs. Members agreed that in these circumstances a recommendation of support should be made to allow access to patient identifiable information without consent.

**ECC 5-02(FT6)/2012 Rate of thromboembolic disease and other complications in total ankle replacement surgery**

This research application from the Royal National Orthopaedics Hospital detailed the linkage of National Joint Registry and Hospital Episode Statistics data in order to provide better understanding of the thromboembolic disease risk associated with ankle replacement surgery. Access to confidential patient information included date of birth, hospital/NHS number, and postcode and gender were requested in order to link the two datasets. The application was considered under proportionate review criteria 4; *Time limited access to undertake record linkage/validation and to pseudonymise the data.* It was noted that the application form included a number of inconsistencies in relation to the identifiable data requested and Members noted that the amount of identifiable data should be the minimum necessary for the specified purposes. The application form did not appear to include evidence that all data items specified were required. Members agreed that linkages could be carried out using NHS number only in the first instance; this would allow the suitability of this data item alone to be assessed, prior to access to more direct identifiers such as postcode. Members agreed that support could be recommended for access to NHS number, age and gender only. If linkage using these data items proved not to be feasible and further data items were required to carry out the linkage, Members indicated that further evidence of the necessity for the extent of data items requested should be provided.

**ECC 5-02(FT7)/2012 National Cancer Survivorship Initiative – Patient Reported Outcome Measures survey of survivors of cancer of the ovaries, cervix, uterus and bladder**

**ECC 5-02(FT8)/2012 National Cancer Survivorship Initiative – two national Patient Reported Outcome Measures survey of survivors of colorectal or prostate cancer**

These service evaluation applications from the Department of Health detailed an expansion to the pilot Patient Reported Outcome Measures survey, which was completed in 2011 and the longitudinal follow – up survey of 2012 [ECC 8-05 (b) 2010]. The applications detailed that following this pilot a policy decision had been made to extend the survey to 4 pelvic cancer groups – ovary, cervix, uterus and

bladder and colorectal and prostate cancer patients. Identifiable data including name, address, sex, ethnic group, year of birth, NHS number, ICD10 code, speciality code and date of diagnosis for each patient would be provided from the cancer registries to a contractor who would administer the survey on DH's behalf. Mortality checks would be made with the Demographic Batch Service to ensure that the patient was not deceased before sending the survey. This application was processed under proportionate review criteria 1; applications to identify a cohort of patients and subsequently seek their consent. Members noted that the two applications specified above followed the same methodology as the previously approved pilot application and agreed that support could be recommended for these two new activities.

**MR1113 Study of Heart and Renal Protection (SHARP)**

This research application from the University of Oxford detailed a request to access follow up data from the NHS Central Register for a cohort of patients who had been recruited to the Study of Heart and Renal Protection (SHARP). This was a clinical trial which aimed to assess the effects of cholesterol-lowering therapy with a combination of simvastatin and the cholesterol-absorption inhibitor ezetimibe among around 9,000 (1,987 from UK) patients with chronic kidney disease. The cohort had been recruited and flagging of 1,745 patients via the MRIS service at the Health and Social Care Information Centre (HSCIC) for deaths, cancers and exits from the NHS was requested. This application was processed under proportionate review criteria 7; validity of consent. The consent forms were originally reviewed by the Data Access Advisory Group at the HSCIC who determined that the consent obtained was not specific enough to allow the release of the requested information. This application had been reviewed previously by the Database Monitoring sub-Group (DMsG) which had been disbanded in 2010 and at this time support had been recommended. It was noted that the consent forms made reference to accessing information from central registries but did not specifically refer to the HSCIC. It was considered to be unfeasible to seek to re-consent the cohort given the retrospective nature of the recruitment. It was agreed that as there was some doubt over the adequacy of consent to cover the disclosure and support had been deemed necessary in the past, a recommendation for continued support under the Regulations should be provided to provide a clear legal basis for the disclosure.

**Amendments**

**ECC 5-04(L)/2011 Using evidence to reduce risk of healthcare acquired infection following primary hip replacement**

This application proposed linking data from several data sources (the National Joint Registry (NJR), the Health Protection Agency Surgical Site Infection Surveillance Service (SSISS) database, Hospital Episode Statistics (HES), Patient Reported Outcome Measures (PROMS) and ONS mortality data) in order to allow the assessment of the cost-effectiveness of infection control strategies for hip replacements performed in NHS hospitals and to make recommendations about which infection control strategies should be implemented. Approval under the Regulations was requested as name, NHS number, date of birth, postcode and date of death were required for linkage purposes. An amendment request was submitted which detailed that local patient identifier was required in order to ensure that linkages could take place with data which was submitted and did not include all of the specified data items. It was noted that the local patient identifier would be used for linkage purposes only. As this amendment would not result in an increase in the identifiability of the requested data this amendment was considered by the NIGB office and recommended for approval.

**ECC 8-02 (FT2)/2010 - Predicting Response to Chemotherapy in Malignant Melanoma: The role of DNA repair genes.**

This application from the University of Leeds set out to study patients with advanced melanoma. It was noted that this leads to poor prognosis and that while the majority of patients receive dacarbazine chemotherapy, currently response to chemotherapy cannot be predicted and there is little insight as to why melanoma is resistant to chemotherapy. The study set out to investigate the hypothesis that DNA repair genes are overexpressed in melanoma tumours and the assessment as to why melanoma tumours are so resistant to chemotherapy. As such, the aim was to confirm the significance of DNA

repair gene expression on response to chemotherapy in primary melanoma tumours in a larger sample set. In terms of identification of potential participants, these would be identified using trial data centres (EORTC), at clinical centres by recruiting clinicians or by study coordinators at the University of Leeds for epidemiological studies. For those identified at trial centres, patient details would be sent securely to the clinician who recruited the patient to the trial allowing them to trace required tissue samples locally. An amendment request was submitted which detailed three potential changes to the study protocol:

1. To allow a research nurse from the University of Leeds to access data at one of the research sites, the Christie Hospital, in order to identify tissue samples.
2. To clarify the projected end date, clinical data collected and inform the Committee that patient gender would be included within the data set.
3. To add an additional site to the study and collect data relating to patients who had not be involved in clinical trials, but had received temozolamide (TMZ) or dacarbazine (DTIC) chemotherapy as part of routine clinical care within clinics in Leeds.

Members discussed whether consent could be obtained from patients being treated within the clinic in Leeds; in particular it was noted that only 11 patients would be alive at this point. The applicant asserted that these patients would be terminally ill and that it would therefore not be appropriate to approach them for consent; in addition the patients had been involved in other trials in the past and therefore were aware that their data was used for other research purposes. Members agreed that a recommendation of support could be provided for all patients treated at the clinic in Leeds and for the above specified amendments. It was recommended that the applicant should make reasonable efforts to inform the patients who were still undergoing treatment, to ensure that Data Protection Act requirements were met and that if a patient wished to dissent from the use of their data they could. Members suggested that posters could be displayed.

**ECC 2-06(a)/2009 Small Area Health Statistics Unit (SAHSU) Health Database**

This application from the Small Area Health Statistics Unit (SAHSU) detailed accessing patient confidential data within datasets on births and stillbirths, cancer, mortality, NCAR, MINAP and HES data for the purposes of advice provision, development of methodology to interpret health outcomes for small areas, and to act as a centre of expertise. This post coded health data would be held for a period of 5 years until April 2014. Confirmation was requested that access to gestational age and ethnicity within linked ONS birth registration and NHS Numbers for Babies information would be included within the current approval. It was noted that the original application included obtaining this information through linkage of ONS births and HES data. However, ONS had specified that these data items were obtained from NHS Numbers for Babies data and their application for support under the Regulations (PIAG 4-05(d)/2005 Access to Birth Notification Information for Statistical Purposes) covered this access. Additional confirmation was therefore requested that the approval included access to this information. As access to this information was included within the original application and the only deviation from this was a change in data source, this amendment was considered by the NIGB Office who noted the change and recommended continued support.

**ECC 1-06 (d)/2011 UCL NICOR processing of cardiac audit data – cause of death addition.**

The amendment to the audit application requested access to cause of death for the six audits that NICOR currently have support to process. The rationale for this amendment was to more accurately classify deaths that follow a specific cardiac event so that non-cardiac causes could be identified. This was considered to be particularly important given NICOR-UCL's aim to provide information about service providers to those patients wishing to make choices or assure themselves about the quality of local services. Publishing both total death rate and a new rate adjusted by cause would reflect local performance more accurately. This request was considered via Chair's action and it was agreed that this was a reasonable request, in line with the purposes of the original application, and would support the work of NICOR. As such, it was agreed to recommend to the Secretary of State for Health that this amendment be approved

**Update on previous applications**

**PIAG/BPSU 2-10(a)/2005 - HIV/AIDS Study**
**ECC 6-07 (FT1)/2009 - Outcome of antenatal syphilis screening**

Following consideration of the advice provided in relation to the two annual review reports received in August 2011, the SofS had determined that the application should no longer be approved under these Regulations, and a letter to the applicant dated 2 March 2012 had advised that the confidential patient information collected would fall within the remit of the NHS Trusts and Primary Care Trusts (Sexually transmitted Diseases) Directions 2000 ("The Directions"). It was advised that in these circumstances disclosure of confidential patient information would be governed by the Directions and the Health Service (Control of Patient Information) Regulations ("The Regulations") would not apply. At this time the applicant had been advised to liaise with colleagues at the Department of Health to discuss progressing these activities. It was confirmed by Department of Health colleagues that both of the studies could be classed as supporting the "treatment or prevention" of sexually transmitted disease, as defined by the Directions, and therefore the Directions did not provide a barrier to the disclosure of information for these activities. On the basis of the additional evidence supplied and the legal advice obtained by the Department of Health it was understood that much of the processing of data within the two specified activities would be carried out under an exemption specified within the Directions as the data would be derived from NHS trusts. However, it was understood that there might still be circumstances in which support under the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information outside the common law duty of confidentiality would be required (e.g. from organisations not covered by the Directions). Where this was the case it was agreed that support could be recommended.

**ECC 3-03 (f)/2012 Mycobacterium abscessus in Cystic Fibrosis: genetic variation, intracellular Behaviour and Clinical Correlation**

This research application from Papworth Hospitals NHS Foundation Trust set out to investigate the biology of the organism *mycobacterium abscessus*; to identify whether there is a clinical correlation between its genetic makeup, how it appears in the laboratory and disease patterns. This application was originally considered on 30 May 2012, where the Committee had advised that due to the relatively small cohort size, it appeared that a BPSU-type methodology could be applied whereby local staff could identify and extract de-identified information to be transferred to the researcher. The Committee had not previously recommended support to the Secretary of State on the basis that a reasonably practicable alternative appeared to be feasible. A letter was subsequently provided by the applicant, setting out a number of points including the importance of obtaining an accurate dataset, issues experienced locally by clinical teams and difficulties in extracting data by those not familiar with the overall dataset complexities. The thoughtful response was appreciated by the Members, and they focused particularly on the comments around the need for accurate collection of the data, the complexity of the dataset, the need for standardisation within the methodology and requirement for 100% ascertainment. It was agreed that the need for 100% ascertainment was a valid one, and this had previously been accepted by the Committee in initially recommending pursuing a BPSU-type methodology. The letter set out the complexity involved in extracting the data and the factors taken into account when identifying the correct diagnosis; highlighting that treatment involves multiple drugs over many years with changes involved during this period. Members considered that a clear argument had been presented on the importance of accurately collecting data on the complex dataset. Members also concurred with the view that due to this complexity that it would be very difficult to standardise data collection at each site by the relevant clinical teams. It was agreed that there was a real risk this could lead to inaccurate data collection that would be of detriment to the study. Members therefore concluded that the study was an important one, and were sufficiently persuaded by the views in relation to the complexity of the dataset, clinical diagnostic complexities and the need for standardisation, to recommend support to the Secretary of State for Health.

**PIAG 2-05 (b)/2007 Secondary Uses Service – Commissioning Datasets addition**

Following amendments being submitted to the Information Standards Board, advice was sought on whether the changes continued to fall within the scope of the original approval. This request was considered by Dr Coyle and it was confirmed that the items continued to fall within the scope of the original application.

**National Renal Dataset – ISB submission**

Approval was recently sought via the Information Standards Board (ISB) to amend the National Renal Dataset (NRD). This request to amend the NRD prompted a need for an assessment as it involved two bodies already with support. It was confirmed that the National Renal Dataset represents a theoretical change with no additional collection of data items other than those already contained within the UK renal registry data set and that of NHS Blood and Transplant. Both of these organisations already hold current 'section 251' approval to collect the data items for specified purposes. It was confirmed that there would be no further data flows outside these organisations, other than those already approved. Should there be an onward dataflow, this would need to be reviewed as an amendment to the existing support.

**Case Register for the Forensic Division (unreferenced)**

This application from Nottinghamshire Healthcare NHS Trust had previously sought advice at an office level in November 2011. The query was resurrected and a draft application submitted. Following review and advice, this application was subsequently withdrawn by the applicant as greater clarity was required on whether support was sought for development of a case register, the requirement for follow-up data, or use of the case register for onward research purposes. It was advised that an application should be submitted once plans were sufficiently mature and alternatives explored.

**3. For consideration**

**3a. Health and Social Care Information Centre transition to new powers**

Ms Clare Sanderson, Executive Director of Information Governance at the Health and Social Care Information Centre (HSCIC), updated the Committee on progress to date regarding transition to the HSCIC's new powers beyond 1 April 2013 and the corresponding impact on the HSCIC needs in relation to support under the Regulations, noting that the HSCIC currently serves as data controller for some datasets and data processor for others. An updated data linkage service had been recently launched and a de-identification standard in relation to publication was being progressed via the Information Standards Board, to dovetail with the new Code of Practice on Anonymisation being produced by the Information Commissioner's Office (ICO). In relation to the de-identification standard, the Committee was advised that the HSCIC were intending to transfer information to an academic organisation; the purpose of this transfer was to test whether the data could be re-identified. The Committee advised that further support under the Regulations would not be necessary as any potential disclosure could be managed via strict local governance arrangements.

Ms Sanderson advised the Committee that the HSCIC was developing a Code of Practice for Confidential Information, in line with requirements of the Health and Social Care Act 2012, which would be published by 1 April 2013 and would be reviewed by a number of stakeholders including the Department of Health, NHS Commissioning Board, Care Quality Commission, Public Health England, British Medical Association, representatives of the independent healthcare sector and patient engagement via NHS Connecting for Health's patient and public involvement group. The HSCIC would be required to work with current and prospective data users to support national data collections, assess the burden of collection and minimise duplication, with all relevant advice given by the HSCIC to be available in the public domain. The HSCIC's new powers from 1 April 2013 onward, include the power to collect and disseminate data as long as the recipient has a legal basis to receive it and the power to require health and social care organisations to provide data as requested by defined organisations.

Members welcomed the helpful discussion and presentation, and the presentation provided by the HSCIC is available as an annexe to the minutes. Members did note that the sanctions available for misuse of data should also be updated within the presentation.

**3b. Health Protection Agency annual review**

This annual review of the specific support provided to the Health Protection Agency under the Regulations, following the framework previously agreed, set out details on compliance with the fair processing principle of the Data Protection Act 1998 in terms of distribution of patient information leaflets, an update on activities carried out under the Regulations, and an update on the Sexual Health Directions. Members also had sight of previous communications that had taken place between Professor Kessel and Mr Knight (Department of Health) in relation to the Sexual Health Directions, and communications in relation to the HARS dataset, and considered there was sufficient clarity in these response letters that did not require further consideration by the Committee.

Members noted that there was a continued requirement to carry out important public health activities under Regulation 3; however the need for reliance upon this by the HPA had reduced due to increased powers obtained through the Health Protection (Notification) Regulations 2010. If not already complete, Members advised that the HPA should take steps to ensure that they are clear which activities are being carried out under other statutory regimes, and this should be documented. This was considered highly important due to the establishment of Public Health England as this would prevent confusion in the future. Members were broadly satisfied with the detail provided within the annual review, and welcomed this clarity. However, Members commented that section 3, point 8 mentions where a project is very similar to an existing approved project, the Committee need only be informed that the activity is proceeding. Members were concerned over this aspect as the issue of similarity is not defined and often small differences might require an amendment or could take the activity outside the scope of the Regulations. It was therefore reiterated that if an activity is similar to an approved application, advice must be sought from a member of the office prior to such an activity taking place so as to provide assurance that the activity is in fact covered under the Regulations. In conclusion, Members therefore agreed to advise the Secretary of State for Health that this annual review should be approved, subject to seeking office advice on similar activities.

Members also advised the HPA to clearly document and specify those activities that were covered by existing other statutory regimes, and those that continued to require support under the existing Regulations, so as to avoid confusion in the future and in particular to support a planned transition to Public Health England, through which it was understood some activities were already progressing. Members encouraged the HPA to engage further with the Committee to review what was covered under the broad definition of communicable disease surveillance within the Regulations. Finally Members noted that the annual review report had made reference to a class application (ECC 5-04 (l)/2011) that was not processed under the HPA's specific support, and reminded the HPA that the latter application would need to be covered under its own scheduled annual report at the appropriate time. It was agreed that for historical reasons, the additional two applications considered by PIAG (pre-2009) in 2003 and 2005 should continue to be reported against, but any other class application should provide an individual annual review at the respective time, to enable clarity on what activities had been carried out under which legal gateway.

**4. Resubmissions**

**Access to historical NSTS database to support National Cancer Registry Migration [ECC 4-03(d)/2012]**

This application specified that each cancer registry was in the process of migration of their individual systems to EnCORE so that there would be one system holding cancer registration data. The overarching purpose of the application was to improve the accuracy and data quality of data related to cancer registration. In particular, support was requested to cover receipt of a duplicate copy of the National Strategic Tracing Service (NSTS) database in order to identify and resolve approximately 40,000 historical duplicated entries within the current cancer registration systems; review of the database

to search to identify potential matches and to manually resolve using associated address history; and during the review, to update details of GP at diagnosis where entries were missing.

Members reviewed the previous outcome, queries posed and responses provided. Members had originally considered that insufficient justification had been present to enable a recommendation of support to be provided, and had deferred providing advice to allow further justification to be put forward. Members had primarily sought clarification on why it was considered essential that these potentially duplicated register entries be resolved, considering the small percentages involved in comparison to the whole; which aspects would specifically benefit from the inclusion of this data; why 100% accuracy level within EnCORE was considered essential and in the public interest; and further information on the data flows. Members welcomed the thoughtful and helpful responses and agreed that as a whole a strong justification had been provided. In reviewing the responses provided, Members agreed that the applicant had adequately addressed the queries posed. In particular, it was agreed that the aspect around utilising the cancer registration system to develop patient access to records was the most compelling, and as the duplicated entries originated from pre-2004, the NSTS database would provide the relevant information. It was therefore agreed that it would be important to improve the accuracy of information held within the merged cancer databases, and it appeared that this was the most appropriate methodology to identify and remove duplicated entries. On balance, the Committee agreed to advise the Secretary of State that this application be approved, subject to standard and specific conditions of support.

## 5. New Applications

### 5a. Clinical Practice Research Datalink (CPRD) overall system approval [ECC 5-05(a)/2012]

CPRD is the output of a government commitment for a managed health research data service where anonymised linked NHS data is utilised within research activities. The processing and linkage of confidential patient information would be carried out by the Health and Social Care Information Centre (HSCIC), under governance arrangements agreed by the MHRA (CPRD). Patient identifiers would be separated from clinical research data at data source origin, and the HSCIC would receive the patient identifiers and carry out linkages on behalf of CPRD through their Trusted Data Linkage Service. This application included details of the main application, the memorandum of understanding with the HSCIC, proposal for a system of approval for dataset linkage within CPRD by ISAC, REC favourable opinion letter, data stewardship diagrams and practice information leaflets. The Committee recognised this application to have huge value and that it would provide a wealth of benefits in the provision of anonymised datasets to meet researcher requirements within the life sciences. Members therefore unanimously confirmed that they were supportive in principle of this activity. It was also understood that Dr Parkinson was unable to attend on this specific date due to prior notified commitments, and Members welcomed the attendance of Dr Tim Williams and the helpful contributions by Ms Clare Sanderson from the HSCIC.

It was highlighted that in terms of advising whether an overall application should be approved, the Committee operate within a relatively defined legal framework; a level of specificity was necessary to comfortably bring this broad application within the scope of these Regulations. The purposes for which data items would be required were considered key to bringing this application within this framework and to enable the Committee to provide a recommendation. Appreciating that the broad nature of the application could make this aspect challenging, Members were clear that the medical purposes needed to be specified and articulated, to a granularity more specific than that of ‘medical research’, with the need for individual identifiable data items to support that specific medical purpose to be correlated and justified; this would then enable a level of specificity to enable the application to be brought within the scope of the Regulations. Members considered that the disclosure of confidential patient information to the HSCIC, so as to enable the HSCIC to carry out relevant linkages, was the significant part of the application. Members were therefore highly supportive of this aspect, but requested greater clarity on which additional datasets would be sent to the HSCIC that they did not currently receive, and which of these would be covered within the HSCIC’s own powers after April 2013. Clarity was requested on these aspects as Members noted that some of the data collections would be covered within the forthcoming statutory powers of the HSCIC and would therefore constitute an exit strategy from these

Regulations. The continued flow of data for some data types might require the need for continued support post-April 2013, therefore the Committee were clear that it would be essential to have these aspects documented in order to be able to recommend an appropriate approval.

It initially appeared from the application that the CPRD would not be processing confidential patient information under these Regulations. However, there was the indication that date of birth would be transferred to CPRD (within the example of neonate studies) and date of death generally. There was also mention of onward disclosure of date of death to researchers. The Committee considered these to be identifiable based on where the data was obtained from, and therefore requested reconsideration of the definition of identifiability. Members concluded that if transferral of these data items to CPRD were considered essential, then there would need to be a clear justification of this, specifying the purposes under which these data items would be transferred to CPRD, and providing a clear rationale for each type of instance. It was also noted that the MHRA would need to complete a satisfactory IG Toolkit submission if intending to process personal data under these Regulations.

The cover letter also set out a proposal that some of the governance functions of approving applications for specific linkages would move to the MHRA Independent Scientific Advisory Committee (ISAC) and a proposal paper was included on this particular aspect. Where it was proposed that ISAC approve linkage of data items, the Committee were clear that it could not recommend support as it would in effect be delegating an advisory function under the Regulations, which the Committee considered was not currently legally feasible under the Regulations. It was suggested that this aspect be taken forward and clarified via the relevant DH sponsor. It was agreed though that it would be highly appropriate for ISAC to review the potential identifiability of the linked datasets, especially as the number of linkages could exponentially increase the potential for re-identification, so as to establish whether further approvals would be required and the Committee suggested that they would be open to working with ISAC to help embed this. Members noted that unless another statutory gateway was identified, a suitable mitigation could be the development of a proportionate review process, specific to CPRD applications that could be developed within the Committee where each new data linkage involving identifiable data could be considered under a streamlined but robust advisory route. It was suggested that a working group could be convened to establish the process, once clarity had been obtained over the overall application. The Committee highlighted that it could only recommend support in relation to NHS-generated or commissioned patient information in England and Wales.

Disclosure of sexual health data remained a concern for the Committee, for the reason that some relevant data collections might be covered by the Sexual Health Directions. In those instances, the Regulations could not be applied as disclosure was governed by the Directions. Where access to sexual health data was not governed by the Directions, the Committee considered that access to these sensitive data items required a higher justificatory threshold, due to the higher levels of confidentiality typically around these types of data collections. Therefore, if identifiable sexual health and sensitive data, such as terminations, was required, then specific and justifiable reasons would be needed to enable the Committee to recommend support. Access to sexual health data was governed by potentially a number of different legal regimes that were due to change, therefore it was advised that the origin of these sensitive data types be identified, so as to enable identification of the correct legal regime that applied, and at that point a detailed rationale for collecting necessary relevant data items, in line with the previous comments on purposes and items, should be provided to enable this aspect to be taken forward.

Concern was expressed about the responses to consent and dissent. It was indicated that proposed changes to the NHS Constitution might be able to rectify this issue, but this would only cover NHS data and the scope of linkages would be likely to extend past this. Members were also unclear on whether the proposed changes would be enacted in time to cover CPRD compliance with the Data Protection Act 1998 in terms of fair processing and managing expressions of dissent. It was advised that the CPRD engage with the Information Commissioner's Office (ICO) and seek advice on how there was sufficient compliance with the Data Protection Act (DPA) 1998 in their capacity as data controllers. This was considered essential as Section 251 of the NHS Act 2006 explicitly states that any approvals cannot be inconsistent with the DPA 1998. The Committee instructed the applicant to provide evidence of the discussions with the ICO, their outcome, and any advice intended to be provided to data controllers

submitting data to CPRD to assist them in ensuring appropriate DPA compliance, as part of the resubmitted application.

The Committee understood the applicant's wish to keep potential approval at a broad level, but felt it might be difficult to comfortably recommend support for the stated data types, rather than data sources. Appreciating the need for this general level, this caused difficulties in terms of being clear what could be approved. Members advised that where data sources could be anticipated, as there was for some, a list should be maintained of the 'core dataset/sources' and what was covered within these. This could be an active list that was added to when new datasets were identified. This was considered important in, for example, access to data from Public Health England, as this would involve other non-NHS activities that would fall outside the remit of the Regulations. In essence, the Committee advised that when specific datasets were identified, and the purposes for which they were required were clear, this could then be assessed within the context of the Regulations as it would provide an appropriate level of specificity. The Committee reiterated that the key aspect to enable a recommendation of support was a clear separation and articulation of medical purposes, in order that the corresponding identifiable data items required to achieve each of these purposes could then be justified in the context of the respective medical purpose.

**5b. Life Study [ECC 5-05(b)/2012]**

This research application from University College London detailed a birth cohort study that aimed to track the growth, development, health, wellbeing and social circumstances of over 100,000 babies. The application detailed two different components; maternity and national. The maternity component required confidential patient information to be sent to MRIS at the Health and Social Care Information Centre (HSCIC) from maternity units, who would then write to pregnant women to invite them to an appointment. The invitation letter would include a covering letter from the NHS obstetrician from the maternity unit. Consent would be taken at the appointment for further inclusion into the study. Support was also requested to allow the retention of dates of birth, ethnicity and deprivation score for those who did not respond to invitations in order to analyse demographics of non-responders. These would be retained until response rates and characteristics had been calculated. The national component of the study detailed recruiting women via MRIS using NHS central register data. MRIS would identify women who met the inclusion criteria and would send invitations on behalf of the researcher.

Members agreed that the outcomes of the application would be in the public interest and noted that the request to process confidential patient information without consent was limited to a small part of the application, in order to facilitate consent being sought from women. Members were pleased to note that the applicant had provided detailed responses to queries preceding the Committee meeting and agreed that it had been useful to be able to raise these prior to the application being discussed. Members thanked the applicant for this additional information. As support under the Regulations could only be recommended where there were no other practicable alternatives Members were required to consider whether alternative approaches to the use of patient identifiable data without consent might exist. In line with this Members queried whether the applicant had considered an opt-in approach via the clinical care teams. Further information had been provided from the applicant which evidenced the difficulties in utilising an opt-in approach. Members discussed in particular the applicant assertion that clinical care teams would have insufficient capacity to approach each woman individually and agreed that it would be unlikely that this approach would be feasible.

Members discussed responses to concerns that had been raised regarding contacting women who had declined to take part in the maternity component of the study to invite them to take part in the national component. Members had queried whether it was appropriate to contact women again in these circumstances. The applicant explained within the query responses that the nature and commitment involved in both studies was very different and that the national component would be far less intrusive. For this reason the applicant considered that contacting those who had declined the maternity component would be appropriate. In addition, it was confirmed that women would be provided with an opportunity to opt out of any future contact within their response to the maternity component and that those who did so would not be contacted for the national component. Members agreed that they were

persuaded by the differences between the two components and were pleased to note that women would be provided with the opportunity to opt out of all future contact.

The proposed involvement of MRIS in identifying and contacting the national component was discussed. It was noted that the Health and Social Care Information Centre (HSCIC) did not have approval under the Regulations to contact patients directly and that currently these requests were considered on a case by case basis as an amendment to their application for the NHS Central Register application. Members agreed that it would be appropriate to recommend support for MRIS to contact women in this instance as this was a national study involving a random sample and facilitating contact via clinical care teams would be likely to involve more confidential patient information being disclosed.

Members noted the information provided by the applicant in relation to public and patient involvement that had taken place so far. Members were concerned that the application specified that patient and public involvement had not been anticipated as a requirement in the tender for Life Study. It was reiterated that where patient information was to be used without consent it was of particular importance to ensure that patient involvement was undertaken. In line with this Members queried whether focus groups had been asked specifically about the acceptability of MRIS writing to patients without consent.

Members noted that there were some inconsistencies within the application form in relation to the retention period for data, for example question 52 specified that data would be retained for 20 years in line with MRC guidance however question 53 stated that data would be held for 150 years. Members requested clarification in relation to this aspect.

Members agreed that their initial concerns had been adequately addressed, that the minimum requirements of the Regulations had been met and recommended that support should be provided to allow the consent aspect of the application to take place. This recommendation would be subject to satisfactory clarification of whether focus groups had been explicitly consulted in relation to the use of confidential patient information by MRIS and the acceptability of this approach, clarification of intended patient data retention time, and confirmation that where women had opted out of further contact at the maternity component, they would not be contacted in order to take part in the national component.

**5c. Enhancing the multiagency management of individuals with EMHN [ECC 5-05(c)/2012]**

This research application from King's College London detailed the examination of current practice relating to the management of individuals with severe mental health needs (EMHN) within Cornwall, specifically at those points where they interact with the NHS and the criminal justice system (CJS). The application detailed access to confidential patient information by one researcher in order to extract pseudonymised data and carry out linkages of NHS and CJS data for 100 patients. NHS data to be accessed was held in the RiO mental health system at Cornwall Partnership NHS Foundation Trust. Data sets would be linked using a pseudoID number only.

Members agreed that this was a well presented and strongly evidenced application and that it was important to understand the overlap in patient journeys between mental health care and the criminal justice system. As such, it was noted that there would be a particularly high public interest in the activity taking place. As support under the Regulations could only be recommended where there was no other practicable alternative, Members discussed whether it would be possible to ask a member of the patient's clinical care team to allocate the pseudoID, which the Committee understood would negate the requirement for a researcher to access confidential patient information. Members noted that the applicant had specified that it would not be possible to identify a current care team for some patients and therefore this approach might not be possible. However, the Committee's view was that even though patients might not currently be in clinical care; there would be individual trust employees who would have legitimate access to patient data on the RiO system and Members queried whether this alternative had been explored.

Members concluded that the study was of significant public benefit and were in agreement that support should be recommended if required, following clarification as to whether trust employees with legitimate

access to the RiO system could be identified and asked to pseudonymise patient data on behalf of the applicant.

**5d. Prevention of neural tube defects in ethnic communities in the UK [ECC 5-05(d)/2012]**

This research application from University College London detailed a study which aimed to calculate the prevalence of neural tube defects (NTDs) within different ethnic groups, to map the natural history of NTD pregnancies and to assess pre-pregnancy knowledge, attitudes and behaviour of women with a previous NTD-affected pregnancy. Confidential patient information including name, NHS number, date of birth and postcode was requested to allow the Health and Social Care Information Centre (HSCIC) to access data from BINOCAR registers in order to link HES, BINOCAR and ONS data and provide pseudonymised data to the applicant. The HSCIC would provide the Department of Health (DH) Abortion Statistics Manager with identifiable demographic data in order to allow them to identify the cohort and provide pseudonymised data to the applicant.

Members noted that this application had been submitted with amended data flows after being withdrawn by the applicant previously, and that only demographic data would be transferred from the HSCIC to DH. A study number would be allocated to allow the patient to link datasets. Members agreed that they were supportive of the application and were pleased to note that the new data flows limited the flow of identifiable clinical information as much as possible by separating clinical and demographic data as soon as feasible. Members advised that support under the Regulations could only be provided where an equivalent duty of confidentiality to that of a health professional was owed by the applicant. It was noted that the applicant was a PhD student from UCL and Members queried how it would be ensured that an equivalent duty of confidentiality would be owed in these circumstances.

Members noted that the linked dataset would contain a large amount of data about each patient and concerns were raised that small numbers of particular characteristics might mean that an individual could be unintentionally identified from the dataset. Members requested further information in relation to how small numbers would be managed to ensure that individuals could not be identified within the research dataset. As a whole, Members agreed that the minimum requirements of the Regulations appeared to have been met and that support could be recommended for this application, subject to clarification regarding the applicant's duty of confidentiality and appropriate management of small numbers within the linked dataset to prevent identification of individuals.

**5e. National Drug Treatment Monitoring Systems [ECC 5-05(e)/2012]**

This application was from the National Treatment Agency (on behalf of Public Health England (PHE)) and detailed the continued processing of patient identifiable data within the National Drug Treatment Monitoring System for a number of purposes including:

1. The production of national statistics on drug and alcohol treatment in England;
2. Supporting two indicators in the Public Health Outcome Indicators framework;
3. Provision of data for international drug treatment statistics;
4. Production of detailed management reporting for treatment providers and commissioners;
5. Provision of data to support the annual needs assessment;
6. Provision of data to support PbR pilots for substance misuse;
7. Allocation of local funding from the national pooled budget, based on prior activity levels;
8. Facilitation of cross governments studies relating to drug misusing populations;
9. Supporting operations of the National Treatment Agency (NTA)

The NTA typically obtains a form of consent, and this previous consent had indicated that identifiable data would not be available to government. However, due to organisational change, NTA staff would become part of Public Health England on the 01 April 2013 and therefore civil servants and a part of government.

Support under the Regulations was requested in order to legitimise the continued processing by Public Health England (PHE) of patient identifiable data for all individuals being treated for drug and alcohol

misuse after the 1st April 2013. As PHE was not yet formally established the Regulations could not currently apply to the organisation and it was advised that PHE would need to complete administrative actions to enable any approval to come into effect. Confidential patient information including initials, date of birth and gender were requested in order to de-duplicate data from a number of sources and link with data from a variety of sources including Home Office, Ministry of Justice, Department of Work and Pensions and the Department of Education. Members noted that this request resulted from an administrative change, rather than a change in the purposes for which the information was collected. Members noted that the administrative change would mean that consent provided was no longer valid and a legitimate basis for continued processing of confidential patient information would therefore be required. Members were mindful that support under the Regulations was not an ideal solution in this instance. However, an alternative could not be identified as it was noted that the consent would no longer be sufficient and contact details for patients were not collected. Members were pleased to note that the applicant had committed to informing all those patients who were currently in treatment about the change by April 2013. Members agreed that there was an overwhelming public interest in the activity continuing and since the purposes of processing would not change a recommendation of support could be made in this instance.

It was noted that there were a number of data sources included within the NDTMS and Members reiterated that support under the Regulations would apply to the NHS components of the dataset only. Members advised that alternative arrangements would need to be explored in order to ensure the continued processing of data from third sector organisations and other government departments was legitimate. It was advised that the administration change had resulted in the consent being misleading to data subjects and therefore it was particularly important to ensure that the data was processed transparently and in line with the Data Protection Act 1998. . Members discussed that the applicant should consider how patients who were not currently being treated could be informed of the changes in line with the fair processing requirements of the Data Protection Act 1998. Members agreed that there was no clear alternative which could provide a legitimate basis for the continued processing of NHS data in this instance and, due to the public interest in the activity continuing, a recommendation of support was provided, effective from 1 April 2013 when PHE would be established, covering patient data collected from the NHS only.

This support was conditional on liaison with the ICO to ensure compliance with the Data Protection Act, particularly with respect to dissemination of information to patients who were no longer in treatment, and the applicant was instructed to provide a report on ongoing dissemination at the annual review stage.

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

This confidential inquiry application set out details of a national programme which aimed to assess quality and stimulate improvement in safety and effectiveness in maternal, newborn and infant healthcare by systematically enabling clinicians, managers and policy makers to learn from adverse events. The purpose of the Programme was to monitor, through population surveillance, the frequency of deaths and review clinical practice in relation to maternal, perinatal and infant mortality and morbidity and identify risks that could be attributed to sub-optimal clinical care. These activities were intended to be completed by 2015. Support was specifically requested to enable the following activities and to enable comparison with historical data:

1. Analysis and reporting of national stillbirth and neonatal deaths data for deaths 1 January 2010 to 31 December 2012.
2. Analysis and reporting of national maternal deaths data for deaths 1 January 2009 to 31 December 2012.
3. Collection of detailed de-identified clinical information and copies of anonymised case notes to enable re-commencement of maternal death confidential enquiries for maternal deaths which occurred from 1 January 2009 to 31 December 2012.
4. Resurrection of CMACE data to support these purposes.
5. To obtain identifiable data from the Office for National Statistics (ONS) for all stillbirths and infant deaths from January 2010 onwards, and for maternal deaths from 01 January 2009 onwards.

This would enable the identification of any deaths not notified through the CMACE or MPMN portal.

6. To obtain from ONS identifiable linked NN4B and birth registration data from January 2009 onwards. This was requested for denominator data to enable calculation of mortality rate.

It was noted that, with the exception of item 3 above, all items involved analysis of data which had been collected previously or was being collected via the MPMN portal. The data collection required for item 3 would only involve de-identified data.

Members considered this to be an extremely well-written application that took full account of the confidentiality issues involved and an appreciation for the confidential inquiry methodology. It was also noted that when processed by CMACE, this activity had previously received a recommendation of support, and this application represented a change to data processor and some changes to the original application. Members considered the extent of identifiers requested to be reasonable and proportionate, and the reasons provided for not seeking consent were appropriate in these circumstances. It was clear that pseudonymised information would not achieve the purposes of the application, and it was acknowledged that during 2011-12 activity had been focused on maintaining data collection so patient and user involvement had been limited. However, there were stated plans to hold a stakeholder meeting with parents, voluntary and user groups and charities, relevant Royal Colleges and professional organisations in November 2012. The Committee was also pleased to note the stillbirth and neonatal death charity SANDS was a member of the MBRRACE-UK collaboration. Members strongly supported the re-instigation of the Inquiry component, considered this to be an essential activity and unanimously agreed there was a significant public interest in this going ahead. The Committee therefore agreed to recommend to the Secretary of State for Health that this application be approved, subject to the standard conditions of support around security arrangements (via the IG Toolkit), user involvement, and discussion of any changes or additional projects with the NIGB office in advance of implementation.

**5g. Child Head Injury Project (CHIP) [ECC 5-05(g)/2012]**

This research application from the University of Cardiff, commissioned by HQIP, set out details of a study to undertake a review and analysis of legacy head injury data (previously collected by CMACE as part of a confidential inquiry), so as to produce a series of peer review papers for publication and a report for the Department of Health and devolved nations. Support was specifically requested to enable the following activities:

1. Epidemiological description of children aged under 15 seen in England and Wales between September 2009 – February 2010
2. Study of the mechanism of head injury and recommendations for prevention
3. Assessment of clinical decision-making on selection of injured infants for CT scanning following head injury and compliance with NICE guidelines on management of head injury
4. Transfer distribution for children following head injury and outcomes for those transferred to specialist neuroscience unit compared to nearest district general hospital
5. A study of children (200) with abusive head trauma
6. Linkage of CMACE data to PICANet data
7. Obtain overall numbers of children admitted to hospitals with head injury during study period by age to establish study ascertainment rate.

Members noted that name, NHS number, hospital ID, date of birth, date of death and postcode would be required for linkage and validation, and date of birth, date of death, postcode, gender would be required for analysis purposes. Members noted that the Child Head Injury Project had originally been carried out by CMACE as part of a confidential inquiry, but this application deviated from the original confidential inquiry purpose and a new data processor would be carrying out the activity, hence the need for a further recommendation of support. It was agreed that the access to identifiers was reasonable and proportionate in the circumstances, and that the methodology was appropriate. Members also considered the public interest to be extremely high as head injury was a primary cause of death in children.

As a whole, Members considered this to be a well-written application that set out appropriate measures to protect the confidentiality of this sensitive information, and agreed that the threshold within the Regulations had been met to enable a recommendation of support to be provided. It was noted that HQIP would retain a dataset once completed, but had confirmed this would consist of fully anonymised data, so no further actions were required over this aspect. Members did query the nature of the proposed linkages with PICANet, and sought further clarification on how the linkage process would be carried out, and whether this would include identifiers. It was confirmed by the applicant that this linkage would not involve any identifiers and would simply involve a calculation of numbers to identify whether any data was missed at time of collection. Members therefore agreed to advise the Secretary of State for Health that this application should be approved, although noting that Northern Ireland was excluded from the scope of this approval due to the remit of the Regulations.

**5h. Resilience and Self affirmation in ex IVDU patients receiving treatment for Hepatitis C [ECC 5-05(h)/2012]**

This research application from the University of Sheffield detailed a study which aimed to ascertain the effectiveness of a change in the psychological assessment process for patients about to undergo treatment for Hepatitis C within the Royal Hallamshire Hospital. Support under the Regulations was sought in order for a researcher to access confidential patient information within hospital notes for three cohorts; those treated prior to the introduction of the resilience interview, those who received the resilience interview and those patients treated on a ward (P floor) where the resilience interview had never been used. Records would be screened against the inclusion/exclusion criteria and anonymised data would be extracted from hospital records. Information relating to disease severity, treatment duration and outcome, as well as age, ethnicity and gender would be extracted.

When providing advice under the Regulations the Committee is required to consider whether any practicable alternatives to the use of confidential patient information without consent exist. With this in mind Members discussed that there appeared to be opportunity for some of the study to be carried out prospectively and with consent. The Committee were of the view that consent could be requested from those undergoing the resilience interviews and those treated on P floor prospectively at the time of treatment. Members noted the small numbers involved in each cohort and agreed that even if a number of patients requested that their information not be used there should still be sufficient numbers to achieve the proposed outcomes. Members recognised that contacting patients retrospectively for consent would not be practicable and therefore consent for those that had already been treated on E Floor prior to the introduction of the resilience interview would not be possible. However, Members raised queries regarding why this cohort was necessary, as it was noted that further comparisons would be carried out with a cohort of patients who had not received resilience interviews in another ward (P floor). Members agreed that there appeared to be a practicable alternative to the use of patient information without consent, by carrying out the study prospectively and therefore a recommendation of support could not be provided. It was advised that the applicant explore this alternative in detail.

In relation to the retrospective Floor E cohort only, Members agreed that consent would not be feasible and sought clarification on the necessity to include information for retrospective E floor patients in addition to comparisons with patients treated on P floor who had not undergone resilience interviews.

**5i. Histiocytic disorders in children with congenital anomalies; a population-based record linkage study [ECC 5-05(i)/2012]**

This research application from Newcastle University detailed a study to investigate the correlation between congenital anomalies and histiocytic disorders in a defined geographical region over a period of 27 years (1985-2011) using population based registry data. Support under the Regulations was requested to allow the linkage of data from the Northern Region Young Persons' Malignant Disease Registry (NRYPMDR) to the Northern Congenital Abnormality Survey (NorCAS) data. NRYPMDR would provide NorCAS with demographic data for all patients diagnosed with histiocytic disorder. NorCAS would then identify patients and provide the NRYPMDR manager with further information. Linked data including date of birth, date of death and postcode would be provided to the researchers at Newcastle University.

The Committee agreed that the study would have significant patient benefits and impact the treatment of future patients. It was noted that the small number of cases of the rare disease in question meant that complete ascertainment was important. In addition, the Committee discussed that the retrospective nature of the cohort meant that obtaining consent would be particularly difficult. Discussion focused on the specified arrangements for the retention of identifiable data. It was noted that a linked identifiable dataset would be retained for 5 years for checking purposes. Members recognised that this would be necessary but advised that the link should be retained within the cancer registries rather than at Newcastle University. In addition, Members agreed that postcode and date of birth should be destroyed once deprivation score and age were calculated. Members were pleased to note that the application asserted the strong links between the research team and the Histiocytosis Research Trust. However, it was noted that consultation had not taken place in relation to the use of confidential patient information in relation to this specific study. Members requested that the Trust be asked about the acceptability of the proposed use of data more explicitly for this study.

Members agreed that the minimum requirements of the Regulations appeared to have been met and agreed to provide a recommendation of approval for this activity, subject to confirmation that the cancer registry would maintain the linked data in identifiable format, rather than retaining this at the University; confirmation that date of birth and postcode would be removed from the analysis dataset once age and deprivation score were calculated; and a view from the Histiocytosis Research Trust regarding the acceptability of the use of confidential patient information without consent for this specific study.

**5j. Long term risk of cervical cancer following HPV infection [ECC 5-05(j)/2012]**

This research application from the London School of Hygiene and Tropical Medicine (LSHTM) requested access to patient identifiable data to follow up a cohort of approximately 50,000 women who were recruited between 1988-1993. At recruitment all women provided a cervical smear for routine cytology, from which a sample was retained for HPV testing. The study would compare HPV infection results to cancer and mortality data to determine future risk of cervical cancer. Access to confidential patient information relating to cancer and mortality was requested from the NHS Central Register. Identifiable data including patient name, date of birth NHS number and address would be used to identify patients for flagging. Where NHS number was not known MRIS would provide this to the applicants. Patients would be flagged for 20 years. Data would also be linked with NHS Screening Programmes in relation to women's cervical screening history and HPV results using stored samples for a subset of women (80 cervical cancer cases, 320 controls and a random sample of 100 incident CIN3 cases). This linkage would be undertaken using NHS number and date of birth only. For those women who took part in a later trial, the ARTISTIC trial, HPV results from both trials would be compared using NHS number and date of birth only.

Members agreed that this application would have significant benefits to patients and therefore it was particularly important that the study took place. It was noted that the cohort was entirely retrospective and for some women consent was obtained over 20 years ago. Members recognised that consent would therefore not be feasible in this instance. Members agreed that the minimum requirements of the Regulations had been met and support could be recommended for this application.

**5k. Risk of cardiovascular disease in survivors of testicular cancer [ECC 5-05(k)/2012]**

This research application from the Royal Marsden NHS Foundation Trust detailed a case control study to look at long term morbidities of survivors of testicular cancer. This would include details of myocardial infarctions, acute coronary syndromes, sudden death secondary to any cardiovascular event and cardiac interventions, in order to evaluate the incidence of cardiovascular events within this cohort. Support was requested to access treatment databases from the Royal Marsden Hospital, Leeds Teaching Hospital NHS Trust and MRC clinical trials unit. Identifiable data would then be sent to the cancer registries in order for them to identify patient data and provide linked HES, ONS and cancer registry data to the applicant. A dataset including NHS number, year and month of birth and death would be disclosed to researchers in order to allow linkage to local data from treatment databases. Identifiable data would be retained by the applicant for 18 months in total.

Members agreed that the proposed study had a clear public benefit. It was noted that the retrospective nature of the cohort (those included in MRC clinical trials between 1982-2002) would make consent for the data linkage impracticable. Members raised concerns that the application detailed no public and patient involvement in relation to the specific project and advised that where confidential patient information was to be used without consent the acceptability of this should be tested with relevant patient groups. Members therefore requested that the applicant approach a suitable patient group/charity to seek their input. Members recognised that the cancer registries would have access to confidential patient information as part of their specific support under the Regulations and therefore this aspect of the application would not require additional support. Members commented that the application incorrectly referenced the use of support under the Regulations within question 15-2 of the application and advised that support did not provide an exemption from consent, but was used as a legal basis to allow the disclosure of identifiable data where consent was not possible. Members agreed that consent would not be feasible in this instance and recognised that identifiable data would be required to carry out linkages. It was therefore advised that the minimum requirements of the Regulations had been met and support was recommended for this activity. This was subject to confirmation of consultation with a relevant patient group/charity in relation to the use of patient identifiable data without consent.

**5l. British Paediatric Neurosurgery Group (BPNG) Audit [ECC 5-05(l)/2012]**

This application from the Royal College of Surgeons of Edinburgh (RCSEd) detailed a request to allow the National Cancer Services Analysis Team (NATCANSAT) to access the BPNG audit database without consent in order to carry out a process of pseudonymisation. The BPNG audit database was currently collected and held by the Royal College in an identifiable format without patient consent. Pseudonymised data would be used to carry out an audit of paediatric neurosurgery in England. Access to confidential patient information including name, date of birth and hospital number was requested in order to allow NATCANSAT to allocate a unique audit number to each patient, transfer identifiers to the submitting hospital along with the audit number and destroy patient identifiers within the audit database. Members unanimously agreed that this audit dataset was a valuable resource, and supported in principle its aims and that it would support improved patient care. However, the Committee was obliged to operate within a legal framework in terms of the advice it provided. In particular, section 251 of the NHS Act indicated that any approvals made by the Secretary of State for Health under the Regulations could not be inconsistent with the provisions of the Data Protection Act (DPA) 1998.

In reviewing the current application, it was considered necessary to view this in the context of previously received applications around the processing of the BPNG dataset. Members noted that an application from the RCSEd had been received in March 2011 (reference ECC 3-04 (t)/2011), which requested that approval be provided to allow a legitimate basis for the continued processing of the audit database. It had been noted that the collection of this data for audit purposes did not involve patient consent, and there appeared to be limited evidence of suitable fair processing information being provided. The issue of fair processing was considered particularly important in the context of the further linked application (ECC 3-04 (u)/2011) which sought to enrich the BPNG dataset with HES data. Members had been clear that this was an important dataset with a clear benefit to patients. However, Members had been unable to provide a recommendation of support as there was insufficient evidence to show that there was compliance with the Data Protection Act 1998. Members had been clear that they would wish to facilitate a re-application at that time and had offered the potential to process an application via fast track consideration, once the legal basis for holding the data and the legal risks currently born by the Royal College had been resolved. Ultimately, following consideration of these applications the Committee had requested that the applicant clarify the implications of the Data Protection Act 1998 on the BPNG audit database, taking legal advice where necessary, and a meeting to discuss this application was also offered; unfortunately this had not been progressed.

In reviewing the current application, Members were concerned that the applicant did not appear to have addressed the points raised in relation to compliance with the Data Protection Act 1998. For example, in accordance with the first principle, it was noted that the Royal College did not appear to be appropriately registered with the Information Commissioner's Office (ICO) to use personal data for certain relevant purposes. The Committee reiterated that, whilst it was supportive of the aims of the application, without

assurance that the requirements of the DPA were met a recommendation of approval would not be possible. The current application included a request for the Committee to approve the publication of a paper prepared using data in the audit database. It was advised that approval under the Regulations could not be used retrospectively and as a result it was not possible for the Committee to provide a recommendation of approval in relation to processing that had already taken place, as this would by default be effectively legitimising a data collection where the original basis for this collection was unclear.

In line with previous outcomes, the Committee reiterated that the applicant should clarify the implications of the Data Protection Act 1998 on the BPNG audit database, seeking legal advice and advice from the ICO where necessary. It was also advised that an application of this nature would be unable to be considered in future until detailed evidence of compliance with this Act was provided. Consequently, the Committee could not recommend approval to the Secretary of State for Health at this time. In order to legitimately enable further processing and the real possibility of linking with additional datasets, it was strongly advised that the Royal College contact, as a matter of urgency, the Information Commissioner's Office in Scotland. The Committee also directed that should any further applications be made in the future, a record of the advice provided by the ICO office, and subsequent actions by the Royal College, should also be provided as evidence of compliance with the Act.

**5m. Hypoxic-ischaemic encephalopathy (HIE) definition validation study [ECC 5-05(m)/2012]**

This research application from the University of Leicester detailed a study which aimed to improve the diagnostic precision of HIE in all settings by attempting to validate existing diagnostic criteria for HIE. Cases with features of neonatal encephalopathy would be manually identified using local electronic neonatal database discharge summaries. Around 300 patient profiles would be compiled. 45 of these would be anonymised and then submitted to a panel of local experts in order to generate a consensus diagnosis for each patient. Support was requested in order to allow a researcher to access local electronic neonatal database discharge summaries of all infants born at 35 weeks or more gestation between 1 October 2008 and 30 September 2010. Patient details including name, hospital number, date of birth and date of death would be extracted. Members recognised the assertion that consent would not be feasible in this instance as seeking consent would be particularly distressing and intrusive for parents whose children would have died, be disabled or have severe life-limiting conditions. In addition, it was proposed that complete ascertainment would be required.

Members raised concerns that there were some inconsistencies within the application in relation to what identifiable data would be retained and for how long. For example, it was noted that question 48 specified that identifiable data would be destroyed, however responses to office queries detailed that forms containing identifiable data would be kept and accessed during the study. It was noted that the application followed a confidential enquiry methodology and it was standard practice in these cases to retain identifiers separately from clinical information. Members therefore advised that identifiers should be separated from clinical information as soon as possible, replaced with a coded number and retained separately.

The Committee also advised that support under the Regulations could not be provided where an application was inconsistent with the requirements of the Data Protection Act 1998. Principle 3 of the DPA specifies that the minimum amount of personal data necessary to achieve the purposes should be processed. It was noted that a large amount of identifiable data was to be recorded and retained, including patient name and date of birth. Members requested further justification as to why each identifier was necessary in order to ensure that the minimum amount of data was being collected and retained for each patient. Members discussed the response to the question that requested details of involvement with patients, service users, carers, or members of the public, which detailed that consultation with neonatal consultants had taken place. Members advised that this question referred to patients themselves as they would be the data subjects in this instance. Members therefore asked that details of consultation with patients or relevant patient groups, such as SANDS, in relation to the activity were provided.

Members agreed that consent would not be feasible for this activity and agreed to provide a recommendation of approval, subject to clarification, for each identifiable data item, of the necessity and justification for collection and retention. Any approval would also be subject to confirmation that

consultation had taken place with a relevant patient group and that demographic data had been separated from clinical data within the data collection sheet.

**5n. Effects of Ethnic Background on the Success of ART [ECC 5-05(n)/2012]**

It had been agreed that the Human Fertilisation and Embryology Authority (HFEA) would delegate the handling and assessment of all relevant applications to access their research register under the Human Fertilisation and Embryology (HFE) Act 1990 to the Committee until March 31st 2013. Under this delegated authority, the Committee would consider and recommend to the HFEA whether to grant or refuse permission to use identifiable register information (or to impose conditions upon its use). As data controller of the register, the HFEA would take a final decision on access to the register based upon this recommendation, and then if disclosure was permitted would work with the applicant to enable use of the appropriate dataset. In terms of disclosure of patient information not contained in the HFEA register, for example the linking of register data to other data sources in England and Wales (and Scotland and Northern Ireland until March 31st 2013) the Committee would provide a recommendation to the Secretary of State for Health on whether those aspects should be approved.

This application from the University of Nottingham set out details of a study to identify the correlation between ethnic background and success of assisted reproductive therapies. The application sought access to the HFEA register to carry out a number of analyses in order to test whether ethnic background of the patient could affect their assisted reproductive therapy, in order to identify whether improvements or tailoring of treatments could be made for those from specific ethnic minorities. Although the application did not request access to identifiable information within the HFEA register, to carry out the activity by default would provide access to the whole register and identifiable data items. The intent would be to extract age and ethnicity from the register and there was no stated intention to link to any further data sources. The Committee provided a recommendation solely in relation to accessing the research register as there would be no other disclosures that would require a recommendation of support under the Health Service (Control of Patient Information) Regulations 2002.

Members considered this to be a relatively straightforward application, and while there was limited information on meeting the 'fair processing' principle under the Data Protection Act 1998, agreed that in the circumstances the original information campaign prior to the launch of the research register could be considered sufficient to meet this requirement. It was also agreed that consent would not generally be feasible. The Committee therefore agreed to advise the HFEA that permission to access the research register for the stated medical purposes should be granted in respect of patients whose details were collected prior to 30 September 2009. Members considered that they could not advise on any data subjects whose details had been included on the register after this date, as the assumption was that these would have provided consent for their details to be included within the register and the ensuing research requests, but emphasised that any dissent recorded after 30 September 2009 should be respected and access not granted for the purposes of this application. Members did query whether the need to access data on all couples would be disproportionate, and sought clarification on the position when ethnicity was not recorded. The Committee's recommendation was also subject to the restrictions on disclosure as set out in Regulation 3 and 4 of the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010. Finally, as the applicant was not seeking to link research register data to any other data sources, it was noted that for the purposes of this recommendation there had not been a review of the security aspects.

**5o. Surveillance Study of Severe Self Harm in Children [ECC 5-05(o)/2012]**

This research application from Central North West London Mental Health Trust detailed a study which aimed to identify the number of young people (aged 14 years or under) who severely self-harm in the UK and Ireland in one year. The study would request clinicians to use the CAPSS and BPSU reporting system to report case of self harm and it was anticipated that around 70 cases would be reported in England. Access to confidential patient information including date of birth, NHS number and sector level postcode was requested to allow duplicates to be removed and for index of multiple deprivation to be calculated. Follow up data would be requested using a second questionnaire after 6 months. Members

agreed that this research was of particular importance as little was known about this cohort and the study would help to develop understanding about young people who self harm.

Members agreed that as this study would be carried out prospectively, the methodology was appropriate. Members also noted that consent would be particularly difficult to obtain for this study. It was proposed that complete ascertainment would be required for the study given the rare prevalence of the condition. In addition, Members felt there might be difficulties in obtaining consent given the nature of the patient's situation. It was likely that the parent/carer would be required to provide consent in most instances and members were mindful that there might be some cases where the parent/carer could withhold their consent due to familial circumstances which had resulted in the child being admitted to hospital, for example, where an abusive relationship had resulted in the self harm incident. Based upon this key consideration, the small incidence cohort and need for 100% ascertainment, it was agreed that consent was not considered to be feasible and the public interest involved in investigating this sensitive issue outweighed the breach in confidentiality. Members subsequently discussed whether there were opportunities to inform the cohort that data collection was taking place. Similar observations were made that there might, in some circumstances, be particular individuals who might wish to request that a patient's details were not shared due to the circumstances which had resulted in the child being admitted to hospital. Members noted that information about the study would be publicised on the BPSU/CAPPS website and considered in this instance this would be sufficient. Members agreed that the minimum requirements of the Regulations had been met and recommended support, with the caveat that this would relate to NHS data collected in England and Wales only.

**6. Any other business**

It was noted that Dr Andrew Harris' term of office would come to a conclusion on 31 December 2012 and his final meeting would take place in December. Members expressed their thanks for his chairmanship and agreed that arrangements would be made to mark his departure.

**7. Date of next meeting**

5 and 6 December 2012
7 February 2013