Ethics and Confidentiality Committee Meeting – Friday 2 December 2011

Members:

Dr Andrew Harris (*Chair*), Professor Sir Denis Pereira Gray (*Deputy Chair*), Mrs Pauline Brown, Dr Tony Calland, Dr Patrick Coyle (items 1-5 and 7), Ms Stephanie Ellis, Mr Michael Hake, Professor Julia Hippisley-Cox, Dr Mark Taylor (*Chairing item 2*) and Mr Terence Wiseman.

In attendance:
Mr Rick Borges (*NIGB Deputy Operations Manager*), Dr Alan Doyle *(NIGB Director),* Ms Natasha Dunkley *(NIGB Approvals Manager),* Ms Claire Edgeworth *(NIGB Deputy Approvals Manager),* Mr Martin Frowd (*NIGB Senior Business Support Officer*), Ms Vanessa Kaliapermall (*Department of Health*)(items 1-5 and 7), Mr Sean Kirwan (*Department of Health*)(items 1-5).

Attending for specific agenda items

Dr Julian Abel (*Weston Area Health Trust*)(item 2), Dr Michael Chapman (*National Cancer Intelligence Network*)(items 1-2), Mr John Ford (*Medicines and Healthcare products Regulatory Agency*)(items 3-5), Ms Claire Henry (*National End of Life Care Programme Director*)(item 2), Mr Chris Carrigan (*National Cancer Intelligence Network*)(item 1), Mr Peter Knight (*Research Capability Programme Group Director*)(items 3-5), Mr Tariq Malik (*UK Association of Cancer Registries*)(item 1), Professor Sir Mike Richards (*National Clinical Director for Cancer and End of Life Care, Department of Health*)(item 2), Dr Julia Verne (*South West Public Health Observatory Director*)(item 2), and Ms Kerrie Woods (*Research Capability Programme Head*)(items 3-5).

Welcome and apologies

Apologies were received from Professor Michael Catchpole, Dr Tricia Cresswell, Dr Fiona Douglas, Dr Colin Harper, Mr Stephen Hinde and Dr Jane Kaye.

Declarations of Interest

The following interests were declared:

1. Dr Patrick Coyle declared an interest in item 6 and was not present for the discussion or decision.
2. Ms Vanessa Kaliapermall was not present in the room for the discussion and decision on item 6 as the Chair perceived there to be a conflict of interest.

Agenda Items

1. Presentation from Cancer Registries

The Chair welcomed Dr Michael Chapman, Mr Chris Carrigan and Mr Tariq Malik and noted that work developments were taking place by the cancer registries nationally. Mr Chris Carrigan gave a presentation updating the Committee on work ongoing nationally with respect to data management and use, transparency and communication with patients by the cancer registries. A new electronic data flow for radiotherapy data had been put in place since 2009 to replace a manual one, and two more electronic data flows were planned for 2012, one comprising an outcome and service dataset and the other dealing with systemic anti-cancer treatment data. Work was ongoing on a single new system English National Cancer Online Registration Environment (ENCORE) to replace eight separate systems in use by the different cancer registries in England. The new system would feed data into the Office of National Statistics, to reduce duplication and streamline workload. Eastern and Trent registries had adopted the new ENCORE system and the other six registries were in the process of doing so. This system did not

cover Scotland, Wales and Northern Ireland. The ENCORE system was fully auditable and would encompass all cancer outcomes data within England. There was a need to update information for patients but Members were informed that this would be best done after the National Cancer Intelligence Network transferred into Public Health England. Currently information for patients was available through NHS Choices but was not widely disseminated beyond this.

Mr Tariq Malik advised the Committee that cancer registries were receiving requests from other organisations for release of anonymised data as organisations recognised the particular quality of the data held by the registries. The Office of National Statistics was aware and had advised the National Cancer Intelligence Network (NCIN) to liaise accordingly with the Committee. Dr Michael Chapman added that recent requests included a greater degree of linkage between datasets, variable consent status and in some cases the scope of requests encompassed more than only cancer data. He suggested that these issues might be alleviated by the forthcoming implementation of the new national Clinical Practice Research Data link. A consultation had been launched to assess the support required by researchers from the NCIN in making best use of cancer data, with options including hosting of study data, data linkage and guidance on consent and ethics. Comments from the Committee in terms of responding to the consultation would be welcomed. Mr Chris Carrigan agreed to feedback the concerns and suggestions of the Committee to the next NCIN patient forum meeting, in February 2012.

Members suggested that the NCIN could follow the NHS Information Centre's model for disclosure of fully anonymised data, noting this was within a framework of clear rules and precedents, and suggested that any linkage of data should take place within the NCIN prior to disclosure. It was confirmed that linkage currently took place only within the NCIN or a trusted third party organisation; that recipients of data from the NCIN were not permitted to carry out further linkage; and that any requests for data from the NCIN for purposes other than those stated in current Regulations would continue to be redirected to the Committee. Members highlighted the potential for common de-identification, pseudonymisation and linkage standards to be developed for use with major clinical databases, noting that clear and consistent standards against which to judge an applicant's compliance would be beneficial to the work of the Committee. It was noted that some datasets possessed specific rules for data use which would add complexity to handling data linkage. Members suggested that dataset owners should be involved in setting of new consistent standards in order to facilitate the application process and to reduce duplication wherever appropriate.

Members also requested more effective arrangements for disseminating information to patients, including the right to opt out, in line with the fair processing principle in the Data Protection Act 1998, particularly with respect to linked datasets. Mr Chris Carrigan confirmed that patient information leaflets had been tested through patient focus groups, included clear opt-out processes and were disseminated by clinical nurse specialists. Patient and nurse engagement were ongoing. Less than ten opt-outs had been recorded in eight years but it was unclear whether or not this was because patients were happy with the service or because they did not know about their right to opt out. It was clarified that these patient information leaflets were not available through the private sector as private healthcare organisations were under no obligation to submit data to the cancer registries: however, some patients might access both NHS and private services in the course of their cancer pathway and as a result data on the NHS segment of their pathway would reach the registry. Members highlighted an opportunity to reassess the level of detail and accuracy in patient understanding of the role of the cancer registries with respect to their data, including preferred methods and timescales of communication with patients.

Members discussed the viability of hosting arrangements, and suggested that registries could carry out analysis of data in-house and disclose only the aggregated results to researchers in line with best practice in information governance, where resources permitted. To manage the proliferation of cancer datasets, a facility could be implemented where researchers could submit data to the registries in a secure environment. Additionally registries might be able to host analysed data and provide access to researchers, obviating the need for researchers to hold data externally.

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

As Dr Mark Taylor had chaired the discussion of this item at the 1 December 2011 meeting, it was agreed that he would also assume the role of chair for this item to ensure continuity.

Professor Sir Mike Richards attended the meeting with his team to discuss the application with the Committee. He advised the Committee that the quality and extent of end of life care data currently collected were very poor, consisting only of the place of death and cause of death. The intention was to better assess the quality of care across health and social care for patients in their final year of life, through linking multiple datasets, building on experience from linking cancer datasets. Raising data quality was fundamental to the national End of Life Care Strategy from the Department of Health. It aimed to compare quality of care across providers and disseminate data on quality of care to hospitals and GPs in a meaningful and timely way, in order to drive improvements in care.

Dr Julia Verne advised the Committee that 500,000 people died per year in England thus it was critical to be able to assess whether or not patients' wishes concerning their end of life care were adhered to, through comparing meaningful outcome data to prior care plans. Currently, there were significant variances in the proportion of patients dying in hospital (40% to 70%) due to age, geography and pathology, with particular areas of concern in chronic obstructive pulmonary disease, heart failure and dementia, and a consequent need to be able to target areas of greatest concern for timely intervention. Ms Claire Henry added that the national end of life care steering group included patients and carers who were keen to use data linkage as a quality improvement mechanism.

Members questioned why this application had come before the Committee rather than seeking consent from patients, noting that consent could be sought feasibly during the development of the individual care plan. Members were of the view that a consent based approach would be possible for the End of Life Care Repository for those patients on the Electronic Palliative Care Coordination System (EPCCS). They noted that patients would be provided with patient information leaflets about the EPCCS and were of the view that this should include information about the use and disclosure of their data for secondary purposes and request their consent for these activities. In line with this, members were of the view that consent should be obtained from the patient at the initial point of entry onto the EPCCS. This was considered particularly important in light of recent Government commitments to patients, such as 'no decision about me without me', as patients would not be aware of their inclusion on the repository. The Committee was keen to ensure that an appropriate mechanism to inform patients was in place. Members were concerned that wide access to data stored in the proposed end of life care repository could have a negative impact on patient-clinician interaction.

Dr Julian Abel clarified that the intent was that the EPCCS would be consent based and patients would be able to opt out; the aim of collecting demographic identifiers was to encourage the development of end of life care plans and to allow clinicians to identify patients who would benefit from having one. Dr Abel suggested that evidence supported better patient outcomes if consent was sought at a later stage in the end of life care pathway through reduction of patient anxiety. He also advised that extensive consultation had taken place regarding the End of Life Care Strategy. Professor Sir Mike Richards added that a stakeholder group was in place including patient representative organisations and there was wide support from patient representatives for developing the proposed data repository.

Members highlighted that some databases, including the General Practice Research Database (GPRD), in fact incorporated very good end of life care data, contrary to the assertion that end of life care data currently collected was uniformly poor. The GPRD had received international acclaim for quality. However, it was accepted that there was currently a lack of clarity around alignment between care plans and outcomes in end of life care. Members suggested that in fact end of life care data quality was good in some areas despite the quality of care itself being poor, and endorsed the general intent to improve both data quality and quality of care. However, Members raised concerns regarding the proposal to establish the new data repository including projected death date which was considered highly sensitive clinical information, without patient knowledge and with potentially a large number of professionals able to input data to or retrieve data from the repository. It was also noted by Members that prediction of

death date remained imprecise and as a result prediction data should be treated with additional sensitivity because inappropriate disclosure could result in significant harm, including breakdown of trust between the patient and health services, negative media coverage and depersonalisation and disempowerment of patients. Members noted that existing mechanisms of communication between hospitals and GPs, including discharge letters, could be used in place of a new system as these were already permitted privileged communications without breaching patient trust.

Professor Sir Mike Richards clarified that the proposed repository was intended to cover gaps in the system as currently there was no single database that covered all end of life care, thus indicating the need for a new single database or more comprehensive linkages between existing databases. He noted that the whole system approach would not be limited to hospitals and GPs alone. The intention was that linkage to other datasets would only be undertaken with consent. Dr Julian Abel and Dr Julia Verne emphasised the importance of recording patient's choice with respect to place of death and end of life care but reiterated the suggestion that good quality care would depend upon only taking up patient consent late in the pathway. Consultation had taken place with the medical Royal Colleges and the British Medical Association. Members suggested a Research Ethics Committee view could be sought.

Professor Sir Mike Richards felt that the proposal had not been articulated to best effect in order to gain the Committee's support, and withdrew the application with the intention of resubmitting it to a future meeting following revision. In the resubmission Members suggested that the application could be clarified with regard to the primary care purposes of the established registry and the secondary purposes of the application for support. If the EPCCS were to be principally used for primary care purposes, Members requested that the potential secondary purposes of the dataset were explicit and it was made clear which aspects required support. If the EPCCS continued on a fully consented basis, including consent for access to Hospital Episode Statistics (HES) data for secondary purposes, support would only be required for access to HES data for those who had died and were not on EPCCS. Clear justification for the use of identifiable data from HES for those patients would be required. In addition, patient information leaflets, consent procedures and details of any involvement with patient groups, including consultations, should be included in the resubmission.

3. Presentation from Research Capability Programme – Transitional Arrangements

Mr Peter Knight updated the Committee on transitional arrangements relating to the Research Capability Programme (RCP), including current and future governance structures. The RCP Health Research Support Service (HRSS) had previously received support under the Health Service (Control of Patient Information) Regulations 2002 in order to pilot the 'honest broker' facility in relation to a small number of defined studies. The purposes of these pilots were to test capability delivery, governance arrangements, mechanisms and controls, and identify lessons for future roll-out of the service. The Committee were informed that the pilots had been completed and the intention was to transition the service into business as usual operations; an application would subsequently be submitted to cover this aspect.

The Committee were informed that the Health Research Support Service and General Practice Research Database were intended to combine into a single Clinical Practice Research Datalink (CPRD) service to be hosted by the Medicines and Healthcare products Regulatory Agency from April 2012.

Members understood that the introduction of the proposed Health and Social Care Bill would mean that the NHS Information Centre would also be in effect an honest broker, and members queried what information the NHS IC would hold that the CPRD would not. It was clarified that the CPRD would primarily be for research purposes, while the NHS IC had a broader role in relation to national audits and commissioning requirements. Members also queried the independence of the CPRD and to what extent it would maintain this.

It was noted that there had been a change of the 'Meeting Governance Requirements: Planned future state' slide from the presentation circulated to members. While appreciating that it was clearly a busy time for the presenters, members were disappointed to find this slide unreadable at the meeting and hard copies were not available; therefore they were unable to comment meaningfully at that time.

Members welcomed Mr Knight's commitment to send a revised slide with the information after the meeting as this was considered to be the most important slide.

As a whole and noting this was still at draft stage, members found it difficult to comment on the proposed governance arrangements without having an understanding of the terms of reference for the various boards, their configuration, how they were appointed and accountabilities. It was understood that these had probably not been developed at the time of the presentation; however, it was clear to members that they would be unable to provide specific advice without having these requirements in place.

Views were expressed that there appeared to be a current lack of clarity over the functions of the CPRD and the scope of research that it would support. It was hoped that an application would make this explicit; however, this point was considered important as from experience in advising on applications for support under the Regulations, members noted that not all research could claim the same level of public interest and therefore a justification for any interference with patient confidentiality. In discussing this item, reference was made to the specific support provided to the cancer registries and public health activities as these were predicated upon an understanding of a particular kind of public interest in processing for those relatively specific purposes. In reviewing the slide, members thought it important that the checks and balances to be proposed required independent scrutiny, but regretted this was not currently possible without detailed understanding on how the governance arrangements would operate in practice. In particular, members were of the view that scrutiny should really be provided by Parliament and ideally a legal basis provided within specific support via new or amended Regulations.

At present, and taking into account that not all detail was in place, it was proposed that there was a significant possibility that the existing Regulations could not provide an appropriate route to legal support for the proposed activities. It was noted that support was originally provided in relation to specific studies; the fully operational service would seek to go far beyond this aspect, and therefore this could be stretching the boundaries of the current legal framework. The Committee indicated that such an important resource should have a clearly defined and secure legal basis, and therefore if there was doubt for this processing under the current legal framework this could undermine the perception of the service. Further clarity on the specific role and function of CPRD could resolve this issue, however, it was important to flag this as a concern. Members suggested that the RCP team should discuss this with the relevant policy and legal teams at the Department of Health.

Additional comments were made that GPRD was a pseudonymised dataset, and the implications this merger would bring for those participating practices should also be contained within any application in terms of meeting fair processing requirements. Queries were also raised in terms of onward disclosure to researchers. The HRSS provided de-identified data to researchers, and members sought clarification on whether or not the intent would be to provide identifiable data for specific research projects. If so, an understanding of the governance arrangements and checks and controls in place to manage this would be expected within any subsequent application.

An external reference group and independent scientific advisory Committee would provide independent oversight and this would be supported by separation of duties within the MHRA. The aim was to avoid compromising governance controls during the transition period. Appointments processes were in place to appoint members to the external reference group, scientific advisory group and patient and public involvement advisory group. Training was being audited internally on a quarterly basis and this was set to continue. An external assessment of training had also been commissioned. Discussions were also ongoing with the Information Commissioner's Office on public engagement and opt-out mechanisms.

As a whole, the Committee welcomed the continuing commitment to engage with and address issues raised, and reiterated their support for the concept of the honest broker service. It was appreciated that much work had taken place and that it was clear that greater detail would need to be developed in order for the Committee to effectively advise on the proposed structures.

4. Presentation from Research Capability Programme (RCP) – Lessons Learnt Report

Following the presentation above Mr Peter Knight summarised and discussed lessons learnt from the Research Capability Programme Health Research Support Service (HRSS) pilot and advised the Committee that a single overarching log of all lessons learnt had been established. Evidence had shown that development and review of Memoranda of Understanding between organisations and related documents had taken longer than anticipated. Approval cycles relating to the Hospital Episodes Service were developed; multiple different approval processes were currently in place and some were repeated for each new study, suggesting a need to streamline processes while maintaining rigorous governance controls. A need was also identified for researchers to thoroughly embrace patient and public involvement. The final lessons learnt report would be presented to the programme board in March 2012 and would subsequently be circulated to this Committee.
Members were informed that positive feedback had been received from a variety of sources following the end of the RCP pilot, indicating that the pilot had delivered interim benefits supporting the vision of delivering better patient outcomes, quality and value for money through research and emphasising the UK as a site for health research. Communications and engagement were ongoing and embedded in all staff training, and a detailed presentation on engagement would be given to the NIGB Board Meeting on 6 December 2011.

Mr Peter Knight tabled a report comparing compliance with NHS Number use across a range of different databases, showing an average 99.9% compliance score across national databases but highlighting a need for improvement in local systems, where the level of NHS Number compliance had not changed significantly over the last twelve years. The report was still in draft format at the time of this meeting pending feedback from data controllers. Members discussed that researchers often requested personal identifiers in the belief that the NHS Number would be missing. They praised the high level of compliance indicated across national databases as refuting this assumption and recommended that the NHS Number be used as the primary linking item for data linkage where possible. It was noted however that recording of a valid NHS Number did not necessarily guarantee that this number belonged to the correct patient.

There was not enough time available in which to discuss in detail all the lessons learnt, however, the supporting documentation provided was welcomed. It was understood that the pilot HRSS had provided the dataset for the final study and in line with all closed applications, an end closure report was required. Members would review the supporting documentation and lessons learnt outside this meeting and write to the RCP team.

Action: Members to review documentation and write to the RCP team on what was expected in the end closure report.

5. Presentation from Research Capability Programme (RCP) - Cerner: Health Facts Overview Paper

Mr Peter Knight provided a presentation on an introductory paper entitled '*Cerner – Health Facts Overview'.* It was noted that the paper was presented so as to seek initial advice from the Committee on what was effectively an 'honest broker' proposal, and that this was not an application for consideration under the Regulations. He advised the Committee that Cerner Health Facts were seeking a mechanism to use anonymised data for research purposes, following deployment of Cerner systems to large NHS trusts. The activity included linkage of datasets and potentially identifiable data which could be followed up by a formal application to the Committee. Members noted that the rationale for development of this additional honest broker facility was not clear at the current time as it appeared that the services potentially to be offered by Cerner could be provided by the Research Capability Programme's future incarnation, CPRD, therefore, the potential applicant should be able to demonstrate why they considered it in the public interest to develop a further facility as opposed to using a pre-existing source. This point would be significant in terms of balancing public interest considerations.

Members queried the role of the Department of Health in presenting this activity, as the applicant was a commercial company; however the focus of the Committee would be to advise the Secretary of State for

Health on whether or not the minimum threshold of the Regulations had been met if an application were made. Members noted that the same Regulations applied to both public and private organisations with respect to making applications to the Committee. Mr Knight clarified that the Department of Health's involvement in the activity was to initially present the proposed activity following a request from the University of Oxford to the Department. Members noted that there was precedent for private sector organisations to use NHS data for research to improve quality and outcomes, such as Dr Foster. The expectation would be for any applicant to ensure that they were operating to the same standards or better within the NHS when processing NHS-generated data, such as in terms of meeting equivalent standards of confidentiality and information governance requirements.

Members felt that there was a potentially negative perception from the public when commercial companies sought to access confidential patient information, and therefore it would be critical to ensure that in such instances that the public would be fully informed. It was commented that meeting fair processing requirements and ensuring that the public were fully informed about the potential use of their data would be a core requirement in any application. In line with this, it was advised that the development of this facility be tested with the general public or appropriate patient groups, as this would also aid in consideration of the public interest. Lay involvement in the overall governance arrangements would also be encouraged.

Members commented that detailed articulation of purposes and the governance arrangements in place for ongoing management and onward disclosure of data would need to be clearly defined so as to ensure that data would be anonymised in the hands of the recipient.

The Committee agreed that public perceptions and concerns would be of great significance with respect to Cerner's intentions. It emphasised that the end result would have to show a clear public benefit. Members suggested that proposals from Cerner could be discussed in detail if Cerner decided to submit a formal application to the Committee in the future.

6. NHS Information Centre Data Access Advisory Group (DAAG) Paper

The Committee was asked by the NHS Information Centre whether or not it could provide advice to DAAG on contentious applications where consent appeared not to be valid for the proposed activity. The Chair had sought legal advice from the Department of Health concerning the Committee giving advice to other bodies. It was noted that the Committee should give advice to the Secretary of State for Health which would be cascaded to the Information Centre. Members suggested that in the interest of fostering good working relationship and furthering the public interest via provision of expertise, the Committee should advise the Secretary of State of their willingness to issue advice to the Information Centre subject to his approval.

Members noted that the Database Monitoring Subgroup (DMsG), formerly a subset of the Committee, had moved to the Information Centre and become DAAG. This had been agreed at the time as the subgroup was providing advice solely to the Information Centre. Membership of this group was now in the gift of the Department of Health. Members suggested that the inclusion of one Committee member on DAAG could be insufficient to accurately communicate the advice or viewpoint of the Committee, although noting that Committee discussions usually arrived at a consensus. Members emphasised the importance of not being seen to exceed the Committee's stated remit and authority and highlighted potential precedent for the Committee to be asked to give advice to other bodies if the Information Centre's proposal were to be accepted. It was also noted that there was a potential conflict of interest in balancing public interest in research versus confidentiality within the Information Centre.

Action: The Chair to write to the Secretary of State, setting out the Committee's concerns and seeking clarity from the Secretary of State on how to proceed with the Information Centre's request.

7. Any Other Business

Amendment request PIAG 2-05(e)/2006 Intensive Care Outcome Network Study – ICON

The request detailed access to telephone number from the patient's hospital record as it was asserted that the study was currently experiencing an unsatisfactory response rate and in order to mitigate this it was proposed that telephone number be provided from records to facilitate the consent process. Members considered this via the fast track process in the first instance and advised that as this related to a matter of principle for the Committee this point would be referred to this meeting, in order to seek an outcome and consensus on the overarching principle.

Members highlighted that researchers wishing to telephone rather than write to patients was an ongoing issue for Research Ethics Committees as telephone contact was seen as more intrusive method to obtain patient consent than a letter. It was noted that some researchers developed cohorts of patients who were willing to be contacted by telephone, but agreed that telephone contact was particularly intrusive where no consent for such contact had been given, and should not be routinely used, especially to pursue patients who had chosen not to respond to letters, on the basis that not responding could be seen as the patient's active decision not to engage with the researcher.

Additionally, disclosure of telephone number outside the clinical care team was of particular concern, especially where ex-directory numbers were involved, as inappropriate disclosure of ex-directory numbers could damage the relationship of trust between the patient and the clinical care team. It was discussed that some patients who had registered their telephone number as ex-directory for their own personal reasons, would have then provided telephone number to the NHS services with the understanding it would be used for the sole purpose of their care and treatment. For these individuals the Committee considered that the breach of confidentiality would be particularly high. Members also noted that telephone numbers were more subject to change than postal addresses and therefore the risk of information being inadvertently disclosed to the wrong person was greater if researchers made contact by telephone.

Members suggested that requests for telephone numbers would be likely to rise due to cultural change gradually favouring telephone contact over contact by letter, and emphasised that in any case it should be the clinical care team who should follow up patients who chose not to respond to contact regarding research.

Members were of the view that alternative methods should be explored to ensure that the telephone number provided in the hospital record was not disclosed. Members suggested that it may be feasible for the patient's clinical care team to call the patient to introduce the study or that a telephone number could be obtained from a public record, as long as Research Ethics Committee approval had been obtained. It was advised that the applicant consider these alternatives.

ECC Process Terminology

The Chair reported back from a discussion with the Department of Health Sponsor around proper use of legal terminology, and emphasised that all discussions and correspondence should clearly indicate that the Committee was responsible for advising the Secretary of State for Health and did not have the power to take approval decisions directly. With immediate effect, a senior civil servant in the Department of Health would take on the task of making decisions on behalf of the Secretary of State with respect to recommendations made by the Committee concerning applications received. This would not be the Sponsor in order to avoid conflict of interest.

Farewell to departing Members

The Chair and Members noted that this was the last meeting for Professor Sir Denis Pereira Gray, Dr Patrick Coyle, Ms Stephanie Ellis and Mr Michael Hake, all of whose terms of office were due to expire at the end of December 2011, and thanked the four departing Members for their hard work and diligent service.