ECC Minutes

NIGB

Ethics and Confidentiality Committee

Meeting held on Monday 21st September

Present

Members: Professor Dame Joan Higgins (Chair), Mrs Pauline Brown, Dr Tony Calland, Dr Patrick Coyle, Dr Tricia Cresswell, Professor Carol Dezateux, Ms Stephanie Ellis, Professor Sir Denis Pereira Gray, Mr Michael Hake, Ms Ros Levenson, Ms Sue Parroy, Dr Mark Taylor, Mr Terence Wiseman.

In attendance: Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(NIGB Business Support Officer),* Ms Melanie Kingston *(Deputy Approvals Manager),* Mr Sean Kirwan *(Department of Health),* Ms Zoë Lawrence *(NIGB Business Manager),* Ms Karen Thomson *(NIGB IG Lead)*.

1. Welcome and apologies for absence

Apologies for absence were received from Professor Mike Catchpole, Dr Fiona Douglas and Professor Roy McClelland.

2. Minutes of last meeting [ECC 3-02/2009]

Minutes of the last meeting held on 20/21 July 2009 [ECC 4-02/2009] were approved, subject to minor amendments.

3. NIGB Office Report [ECC 5-03/2009]

Patient Information Advisory Group (PIAG) Annual Report

Members were informed that the final PIAG Annual Report had been published and a copy sent to the Secretary of State for Health. Hard copies had been sent to all ECC members and the report made available on the NIGB and Department of Health (DH) websites. The report covered an 18-month period from June 2007 through to the end of December 2008 when PIAG was closed. The work of the DMsG was also included in the report.

NIGB Annual Report

The NIGB Annual report for 2009 is currently being drafted in preparation to be launched at the NIGB Annual Public meeting on 12 November 2009. The report includes a chapter on section 251 and the work of the ECC and DMsG. Summary tables of all the applications considered since January 2009 were included in the Annexes.

NIGB Annual Public Meeting

Members were informed that the NIGB would be holding its annual public meeting on Thursday 12 November at the Central Hall, Westminster at 2pm. ECC and DMsG members were invited to attend.

Appointment of ECC Chair

When PIAG transferred to the NIGB, Ministers agreed that for governance reasons the existing PIAG Chair would be a NIGB member on a transitional basis for one year. It had become necessary to formally appoint a NIGB member, via the Appointments Commission, who would chair the ECC and would take up post from 1 January 2010. Adverts were placed in the national press in late July, with a closing date of 2 September. The appointment would be ratified by the Appointments Commission during October.

Ascend Study – University of Oxford

PIAG originally approved the Ascend Study in 2003. Recently, the NIGB Office had received two separate pieces of correspondence concerning this study.The first letter was from the General Practitioners Committee of the BMA (Wales) which argued that as patients attended the Diabetes Retinopathy Screening Service Wales annually, this provided sufficient and reasonable opportunity for consent for disclosure to be sought. The second letter was from a patient (in England) who stated they had been contacted directly by the researchers when the conditions of approval stated that the first contact should be made by a GP or clinician. The Office has contacted the University of Oxford for their views on these issues, so that these could be reflected in their annual review due in October.

Secondary Uses Service (SUS)

Following the last meeting of the ECC when members considered SUS's annual review it had been agreed that a further application from SUS would be submitted to the November ECC meeting. NIGB Officials met with Wally Gowing concerning the new application which was intended to detail the full purposes of SUS.

National Research Ethics Conference (NRES) – 24 November 2009

Members were informed that the NRES Conference was scheduled to take place on 24 November at the Russell Hotel, Bloomsbury, London. This conference was a useful forum to make contact with researchers and explain about section 251 and the role of the ECC/NIGB, and a member of the Office would be attending.

IRAS

Members were informed that the NIGB Business Manager attended the IRAS Management Board and Project Board on 21 July. The work to review the NIGB forms on IRAS was scheduled for October, and the integration of IRAS with the ECC application management database was scheduled for late 2010.

UK Clinical Research Collaboration (UKCRC)

The NIGB Business Manager attended the UKCRC Regulatory and Governance Advice Service Network meeting held on 13 August. The meeting reviewed the metrics from the advice service, and the Terms of Reference (ToR) for the Network to become the Advice Service's Management Board. The Advice Service receive a small number of queries from researchers about S251 approval which are generally handled well. Complex queries were forwarded to the NIGB.

Extensions to existing approvals

Application for extension of Case Mix Programme (PIAG2-10(f)/2005) for data collection for SwiFT (Swine Flu Triage) Study

This application sought an extension of section 251 approval to obtain mortality statistics for patients on the Case Mix Programme (CMP), in order to link with the existing approved database. It was noted that the proposed study used the same methodology adopted by other studies in the CMP, and that the proposal for the extension was well developed and clear. This extension was approved by Chair's action.

Fast Track applications

Active prospective surveillance for Guillain-Barre syndrome (GBS and Fisher Syndrome in children)

This study utilised the BPSU methodology to carry out active prospective surveillance in children in conjunction with the HPA. This study was approved by Chair's action.

4. ECC Chair's Report

Vacancy for ECC Member

The Chair noted that Dr Fiona Douglas' term of office would end in December 2009 and Members were informed that the vacancy had recently been advertised. The interviews had been scheduled for October.

Appeal

The Chair reported that an appeal had been received by the NIGB against a previously rejected application; Paediatric Palliative Care in Yorkshire ECC 2-06(f)/2009. Members were informed that the appeal was intended to look at whether the ECC had acted reasonably, according to due process and whether they had come to a reasonable decision on the basis of the information they were given. The appeal was chaired by Harry Cayton and two other members of the NIGB and the unanimous decision was that the ECC had acted reasonably and reached a reasonable decision and that the original decision was upheld.

NIGB Meeting update

The Chair provided an update on the recent meeting of the NIGB that took place on 10 September 2009. Three working groups had met before the formal meeting and discussed the following topics:

a. Information governance and the consent model to be used in the Common Assessment Framework demonstrator sites and social care access to the PDS.

b. The Summary Care Record and consent

c. The Hampshire Health Record

The Board meeting was also preceded by a presentation on the challenges of information governance in a war zone and across national boundaries, by Admiral Lionel Jarvis, a member of the NIGB.

Members were informed that one of the main items of business at the Board was a discussion of the GP Extraction Service. The Board accepted two documents on the extraction process and on information governance principles. It rejected a third paper which related to the establishment of an Independent Advisory Board, on the grounds that it did not appear to be independent, that it had insufficient input from lay people and it was not sufficiently clear how it would work with the DMSG and the ECC. The Chair would be involved in further discussions about these details.

The Chair was invited to a meeting, on September 7th, at the Department of Health (DH) to discuss the DH Research and Development Department's proposals to establish a Health Research Support Service. The intent would be to embark upon a pilot programme which would, essentially, provide a data linkage and anonymisation service for researchers. The NIGB Office would be involved in further discussions around this and would provide updates when available.

5. DMsG (Database Monitoring sub-Group) Report [ECC 5-05/2009]

The DMsG Chair presented a written report on the status of applications and approvals, as well as other issues arising from DMsG's meetings.

Validity of Consent

Members were informed that the NIGB office had seen an increasing number of applications involving historical studies where consent to participate had been obtained, but was not considered valid for the level of information or linkages subsequently requested for long term follow up.

Members were asked to consider the most appropriate course of action to take when doubts were raised by the DMsG about the validity of the consent in place. The NIGB office requested that the Committee consider:

1) If re-consenting was genuinely not practicable, did members consider s251 to be an appropriate alternative?

2) If s251 was considered appropriate could a fast-track process be developed to expedite applications of this type?

Members identified two issues that could arise that would bring into question the validity of consent gained.

- The first related to the length of the study and the length of time that had passed since consent was originally gained. Members felt that there would be some people happy to consent to access to their records at the time consent was gained but that this may change prospectively. For this reason the view was expressed that researchers should revisit consent after a significant amount of time. The Mental Capacity Act 2005 should also be observed in relation to those that might lose the capacity to consent and, in line with this, any dissent from relatives should be taken into account. The Committee agreed whether a cohort should be re-consented in this situation should be a test of proportionality and in many circumstances informing the cohort that they could withdraw at any time would suffice.

- The second issue related to where there had been a change in purpose of the study and therefore a change in use of the information requested. Again Members felt that this should be assessed on a case by case basis.

Members concluded that section 251 could be used in certain circumstances and there should be a process in place to consider applications where consent may no longer be valid and that it would be good practice to establish this. However Members felt this should not be too rigid and that it was important the measure remained proportionate to the situation. It was agreed that the DMsG would refer to the ECC any studies which they decided did not have valid consent and that there was scope for section 251 to be used, where appropriate, rather than re-consenting an entire cohort.

Action: NIGB Office to develop a process to consider applications of this nature.

DMsG Interim Terms of Reference (ToR)

The current ToR for the DMsG had become out of date and much of the content no longer relevant. Members were asked to consider a draft ToR. The draft incorporated comments already made by the DMsG Members.

Members were informed that discussions with the NHS Information Centre (NHS IC) concerning the establishment of the Independent Advisory Group for the General Practice Extraction Service (GPES) were still ongoing and that in the interim, the draft ToR would apply to the DMsG.

Members approved the ToR and these would be placed on the website shortly.

Action: NIGB Office to add DMsG Interim ToR onto website

5. Patient Episode Database Wales (PEDW) Annual Review

Health Solution Wales submitted an annual review outlining the changes in process and administration of the PEDW database. The original application [PIAG 2-05(b)/2005] applied for specific support under section 60 of the Health and Social Care Act 2001 (now re-enacted under section 251 of the NHS Act 2006). PIAG approved the application to proceed to regulations, subject to a number of caveats. At the time there was some confusion about the precise legal status of PEDW following this approval. Support under section 60 (as was) had not been provided for PEDW as the purposes were too broad to legitimately fit under class support, but instead support had been given to proceed to regulations.

The Committee considered the annual review papers provided and reconsidered whether class support could be provided for PEDW. Members were informed that the applicant was currently drafting regulations to seek specific support. Members were in agreement with the previous decision of PIAG that the range of purposes was too broad for class support and therefore it recommended again that specific support through regulation be sought.

When considering the documentation provided, the Committee did note that Wales had been rigorous in their practices and appropriate access to data and welcomed the detailed document setting out the changes and updates. Members expressed concern that in the listed purposes, some related to non-medical purposes, such as publication of statistics, and noted that the statutory basis for collection of this data would need to be considered. Members felt

that those activities where data is collected solely for non-medical purposes should be assessed to consider whether anonymised data would be sufficient for these secondary purposes.

Additionally, Members noted Page 11, of the document and queried the statement “The vast majority of outputs are in the aggregated form but where a business case and security are proven, and subject to an appropriate ethics committee and Caldicott Guardians, record level data is made available (to varying extents and under strict control) for use of specified purposes.” Members requested clarification over these controls and in particular, strongly disagreed with any onward disclosure of patient identifiers without consent or section 251 support.

In conclusion, the Committee were highly supportive of the work of PEDW, were mindful of its importance and sympathetic to the difficulties, but were unable to provide class support under section 251, therefore the current status of PEDW remains. The Committee strongly recommended that specific support be sought via regulations in order to ensure that PEDW’s activities continued on a clear and transparent legal basis.

Action: NIGB Office to inform applicant of Committee decision.

6. Resubmitted applications for section 251 support

a) ECC 4-15(e)/2009: Evaluating stereotactic radiosurgery in brain metastases

This application from University College Hospital planned to establish a research database to evaluate the service provided by stereotactic radiosurgery and determine nationwide practical standards. Section 251 support was required to allow researchers to populate the research database with retrospective/deceased cohort details.

This application was originally considered at the July meeting and at that time, Members had requested clarification whether the database was for the purpose of audit or research. Members had also requested information on the rationale to establish this database.

Members were sympathetic to, and supportive of, the overall purpose of the activity, and were pleased to note that consent would be sought prospectively. Members noted that trials typically require some kind of evidential basis in order to proceed, and as such retrospective data would be valuable. However, it was agreed that the overall intent around the uses of the database were still not clear and Members queried whether it would be a formal research evaluation, or a roll-out of a service.

Members were concerned about the extent of identifiers required without consent and queried, within the defined Centres, whether a more minimal set of identifiers could be submitted. Members noted similarities between this activity and the Vascular Society and Neonatal audits and queried whether date of birth and death were required or whether month and year would be sufficient.

Members also noted that within the application, the activity was marked as a research database and was referred to as a database throughout. However the applicant classed it as service evaluation. Members noted that if framed as a service evaluation, further research could not legitimately be carried out using this data until it was formally converted to a research database, which would involve further submission to the Ethics and Confidentiality Committee and probably a Research Ethics Committee. Members therefore felt that whilst a significant proportion could be considered to be service evaluation, its ongoing use would

generate new knowledge and therefore felt that its overall purpose would fall within research and that the application should reflect this.

The Committee were unable to approve this application on the basis that they were not persuaded this was fully service evaluation in its current form, and there appeared to be some intent within the application form to use this as a research database.

Members requested some clarity over the medium-term intent of the database. They were of the view that in the longer term the overall aims of the database would be for research purposes and as such, a favourable opinion should be sought from a Research Ethics Committee. Once the favourable opinion had been obtained, Members agreed that the full application could be resubmitted, setting out the research purposes, and a decision could then be taken via Chair's Action rather than progressing to full Committee.

Action: NIGB Office to inform applicant of Committee decision.

b) ECC 4-15(f)/2009: Preventing depression relapse with Mindfulness-based Cognitive Therapy (MBCT)

The purpose of this resubmitted application from the University of Exeter was to allow access to GP practice databases and clinical records by researchers with an honorary research contract to identify a cohort with the intention of seeking consent. The study aimed to assess whether MBCT was more effective than anti-depressant medication in preventing depression relapse over a 24 month period as well as several other secondary outcomes which could be used to reflect MBCT's effectiveness. The application was originally considered at the July meeting and was not approved as the Committee had some concerns about the methodology.

The Members considered the responses to the points made in the original outcome letter and were not persuaded that sufficient evidence had been provided. Members noted that whilst the researcher would require access to contact details, this would involve seeing other, more sensitive identifiable information, therefore, the point should be emphasised that the Committee does not distinguish between the purposes of access, and its emphasis is on the issue of the access itself.

Members remained concerned about the status of an accredited researcher accessing GP records to contact patients. A core principle of the Committee is that initial approaches should always be made by a member of the cohort's clinical care team at either the GP Practice or the hospital. The Committee commented that an honorary research contract did not allow a researcher to set aside this principle or allow access to identifiers, and that a number of applications implied that researchers thought this was a mechanism by which to do this. The Chair agreed to raised this issue with the NIGB.

Action: Chair to raise issue of honorary research contracts with NIGB via Chair's report.

In particular, if consent had not been obtained from the patient, the Committee agreed the researcher should not make the initial approach or telephone the patient on the basis of this principle. Any follow-up telephone call should be made by a clinician not the researchers. The Committee considered a telephone call from a person outside of the clinical team would place undue pressure on the patient and therefore any consent given would not be valid in these instances. The Committee were sympathetic to the fact that it is often difficult for GP staff to carry out the activity, due to a number of reasons. However Members queried whether there

was any evidence to demonstrate any of the difficulties experienced on a practical rather than anecdotal basis specifically in relation to this study.

Members were of the view that GP staff could relatively simply run electronic searches to identify the cohort using defined search criteria, and they could then address the letters without involving any disclosure of identifiable information to the researcher. Members also noted that section 251 was only to be used as a last resort and that it cannot be given to overcome administrative issues or lack of resources.

Members noted the extent of service user involvement and were of the view that this could be broader, and suggested contacting the Mental Health Research Network.

Due to the above issues, the application was not approved. The Committee also emphasised that initial contact with the patient should always be made via a member of the clinical team at either the GP Practice or hospital, and not via the researcher should the patient not have provided consent.

Members commented that they had received significant anecdotal evidence that GPs were often not motivated to recruit patients and they were of the view that grant givers should recognise that the selection of a cohort and the anonymisation of records were an essential stage in the research. GP practices should be given the resource to allow practice staff to support research through the provision of anonymised data. It was agreed that the Chair would raise this issue with the NIGB.

Action: Chair to raise issue of funding to support research within practices to the NIGB

Action: NIGB Office to inform applicant of Committee decision.

c) Palliative Care in Children and Teenagers with Cancer

This application from the University of Leeds required section 251 approval for access to deceased patients' details. The study aimed to ascertain what proportion of children and teenagers who died from cancer in Yorkshire from 1990-2008 were referred to specialist palliative care services. The applicant wanted to link the data on two databases; the Yorkshire Specialist Register of Cancer in Children and Young People and Martin House Children's Hospice Clinical Database.

This application requested access to information pertaining to deceased patients which meant the application fulfilled the criteria for the fast track process. For the fast track process a smaller number of members considered the application outside the usual Committee meeting. The fast track process raised a number of queries and it was considered appropriate for this application to be assessed by all Committee Members at its formal meeting.

The Committee initially assessed the extent to which S251 support could apply. The application sought approval to link data held by the Yorkshire Specialist Cancer Register with data held by Martin House. The Committee noted that the Yorkshire Specialist Cancer Registry had approval to process their data under the specific support provided through regulations, but were concerned about the assumption made that as the Register was held at the University of Leeds, and could be physically accessed by the research team, that approval was already in place to use identifiable information on the Register for the purpose of this study. The Committee emphasised that the Cancer Registries were provided with specific support through regulation for a number of defined purposes which did not include their study.

The Committee were clear that despite a member of the research team having access to Cancer Registry data, any onward disclosure must be made lawfully and in line with section 251 support.

The Members also discussed the extent to which section 251 could be used to access Martin House data as this was primarily a privately funded institution although it was part NHS funded. Members agreed that most of the data within the records would be derived from an NHS setting and therefore felt that section 251 could be applicable in this instance.

Members subsequently assessed whether the extent of identifiers required answered the research question, and whether anonymised information would satisfy the question. Members also queried whether it would be possible for the data linkage to be carried out by the Cancer Registry, or for both datasets to be de-identified but with the NHS number to still be in place so that the data could be linked. Following detailed consideration, Members agreed on the basis of the application it appeared that anonymised information would meet the requirements of the research question. The Committee discussed that the information requested would only show those who were referred to the hospice in question. Members felt that in order to obtain an overall representation of the referral rate other models of palliative care would need to be included.

In conclusion, the Committee recognised the importance of carrying out this activity, however, due to their concerns they were unable to approve this application. In this instance, the Committee agreed that a meeting should be arranged with the applicant outside of the formal meeting schedule to support the applicant.

Action: NIGB Office to inform applicant of Committee decision.

7. New Applications for Section 251 Support

a) ECC 5-07(a)/2009 Infections in Oxfordshire: a Research Database (IORD)

This application from the Oxford Radcliffe NHS Trust required section 251 support to create a database with the primary aim to prospectively investigate predictors, trends and outcomes in order to improve the management of infection control. The database proposed would be created through the linkage of data from the Oxford Radcliffe Hospital Patient Safety System, patient administration system records, pathology and infection control database information, with NIHR infection research data. The application sought access to gender, date of birth, GP Practice code, date of death and source of information on date of death for linkage purposes

The Committee considered this to be a clearly constructed application. They were pleased to note that only minimal identifiable data was requested and the justification for requesting this information was clear. Members agreed that consent would not be feasible as information was also required from those who did not have an infection, meaning that the cohort would be very large.

Members discussed the onward disclosure of anonymised information and felt that guidance should be established by the applicant in order to govern who the data would be disclosed to. The NIGB IG Lead informed Members that guidance such as this had already been created by the National Cancer Research Institute.

Action: NIGB Office to circulate the National Cancer Research Institute's Template for Access Policy Development to Members.

Members provisionally approved this application. This provisional approval was subject to the following conditions:

1. Members requested that further user engagement be carried out and more focus placed on the dissemination of the findings.

2. Members noted the controls over onwards disclosure and requested that, when releasing data to third parties, the guidelines specified by the National Cancer Research Institute's Template for Access Policy Development should be adhered to; to include that the recipient should have a legitimate reason for accessing the data and that there was a responsible custodian; there must be agreement not to link the data with other data (unless specified) which might result in the data becoming identifiable, and that the data can only be used for an agreed purpose.

3. Members noted that in relation to onward disclosure section 11-1 states "...an NHS contract or (honorary NHS contract) may be required in some situations, particularly those involving confidential information)..." Members emphasised that as specified by the UK Cancer Research Network an honorary research contract does not provide a mechanism for access to identifiable information for research purposes without the patient's consent, therefore any such access must be in line with this requirement.

Action: NIGB Office to notify applicant of Committee decision

b) ECC 5-07(b)/2009 Prescription Event Monitoring (PEM)

The Drug Safety Research Unit (DSRU) required section 251 support to develop a surveillance monitoring system to detect, assess, prevent and manage the risks of adverse effects of recently marketed medicines. The DSRU conducts pharmacoepidemiological studies using the technique of PEM, an observational non-interventional cohort design. Access to patient identifiable data was required to identify patients receiving treatment, to confirm that they have been dispensed a drug which was being monitored through PEM and identify the prescriber.

Members considered this to be a clearly constructed application and recognised the huge public safety role the DSRU has in this activity. Members agreed that there was an extremely low risk of identifiable data being improperly used and the use of identifiers was clearly justifiable.

Members discussed whether there could be a consent based process for this type of activity and felt that this would not be feasible and that fair processing in line with the Data Protection Act would allow patients to be informed of the proposed data usage.

This application was provisionally approved with no conditions.

Action: NIGB Office to notify applicant of Committee decision.

c) ECC 5-07(c)/2009 Record Linkage of GRPD data with 1. ALSPAC birth cohort 2. Air pollution data

This application from the Medicines Healthcare products Regulatory Agency (MHRA) and the GPRD Group was to extend the linkages already approved by PIAG (PIAG 3-04(i)/2006). The application proposed to extend previously approved purposes to include using data from

patients' primary care record, before the diagnosis of cancer and to follow up post-cancer treatment.

Members were supportive of this extension of purpose and agreed that it would provide valuable research evidence.

Members provisionally approved this application subject to assurances being sought that action would be taken to ensure that the text free fields would not provide identifiable data.

Action: NIGB Office to notify applicant of Committee decision.

d) ECC 5-07(d)/2009 Referral of Possible Donors to Donor Transplant Co-ordinators Database

This application from NHS Blood and Transplant set out the purpose of creating an electronic patient data system in order to assist donor coordinators and other organ donor professionals in increasing organ donation, and to allow feedback to healthcare professionals. Section 251 support was requested to create this database and to populate it with a number of identifiable data items.

Members noted that increasing organ donation has a huge public interest and were supportive of the overall purpose of the database. The Committee recognised that accurate data would be essential for the activity and that identifying good practice was important.

Overall, the Committee considered the application to be somewhat unclear in the articulation of its purposes, and that further clarification was required over other aspects. There appeared to be some answers that did not reflect the question asked. This led to confusion in some critical areas. For example, Members noted that in one question the application stated that families could not be informed about the database, however in another it referred to contacting families of donors.

The Committee had difficulty identifying the aims of the database and whether it was intended to increase organ donations by monitoring staff activity in this area. Members were concerned that that the applicant referred to accessing employment details of staff. Section 251 could not be used for this purpose.

Members queried that if consent was obtained for the donations in the first instance, why consent could not prospectively be obtained for this data collection at this point.

Members did not approve this application due to the issues outlined above and as listed below, and advised that, due to its importance, the application be resubmitted. It was agreed that the NIGB Office would meet with the applicant to discuss the issues arising from the application to emphasise to the applicant that the following points should be fully addressed in the resubmission:

Fully detailed responses should be provided in response to all of the questions within the application form and the NIGB query sheet. This should include details of the data flows; who would have access and at what stages, and the stages at which pseudonymisation would occur and who would carry this out. It should also list the actual identifiers required. The application should clarify the high level purposes of the database before moving into detail about the specific aims.

Clarification over certain areas of the application form would be required. For example in section (l) where it stated “reports will be identifiable on a need to know basis”, Members requested detail about the meaning of this sentence, including guidelines about when this disclosure would be considered necessary. Similar clarification was requested in relation to the response to the third data protection principle which stated “where identifiable data is required the patient consent is sought, where feasible”.

The Committee noted that the intention was to use employment information about healthcare professionals and advised that this aspect should be excluded from the resubmitted application because it is not within the powers of S251.

Action: NIGB Office to notify applicant of Committee decision.

e) ECC 5-07(e)/2009 A case control study to explore the distribution of lower urinary tract symptoms (LUTS) in older people having fallen

The application from University College Hospitals sought to investigate the distribution of LUTS amongst older people and to compare this to the distribution in older people who had not fallen in the year prior to the study. Section 251 support was requested in order to enable researcher access to the attendance register to screen and identify those who had had a fall, and to obtain contact details in order to write directly to the cohort for consent.

Members considered this application in detail and the arguments made to justify this access without consent. They were supportive of the purpose of the application and agreed that this was an important and sensitive area. Taking this sensitive nature into consideration it was discussed that it would be more appropriate if the letter was to come from the clinical care team and this principle should not be waived because a patient was not an in-patient at the time. Members also noted that the application came from a doctor practicing within the trust who was studying for a higher degree.

Members also queried whether the information custodian should be the student themselves and felt that this should be someone more senior such as a Head of Department.

On balance, Members considered that in this specific instance, provisional support be given to provide researcher access to the attendance register in order to screen and identify the cohort, and to obtain contact details. This provisional approval was subject to the following conditions:

1. A copy of a favourable opinion from the research ethics committee to be provided to the NIGB Office before formal approval can be provided.

2. The invitation and reminder letters and information sheet must show the sender as being the relevant A & E Consultant as it is a principle of the Committee that initial contact must be made by a member of the clinical team responsible for the care and treatment of the patient.

3. The Committee were pleased to note that the applicant would be liaising with the patient involvement group regarding user involvement, and requested that an update be provided in the annual review.

4. The Committee requested that the appropriate information custodian for the data should be the Head of the Department and that agreement should be obtained to reflect this.

Action: NIGB Office to inform applicant of Committee decision

f) ECC 5-07(f)/2009 Clinical score to identify high-acuity patients prehospital/in A&E

This application from the University of Sheffield required section 251 to allow researcher access to emergency department notes and hospitals records and to use data collected by the Development and Validation of risk-adjusted Outcomes for Systems of emergency medical care (DAVROS) project. The study aimed to develop a method for predicting patients at risk of death that will be directly useful to doctors treating emergency cases.

The Committee agreed that this study would be of benefit to emergency department staff and patients. The Committee were also persuaded that in this instance consent was not likely to be feasible due to large numbers. They also recognised that some of the data requested had already been collected by DAVROS, which had section 251 approval, and acknowledged that this study would expand DAVROS. It was agreed that the study had a patient benefit and used a well established approach. Members also discussed that access to notes was the only way for sufficient information to be gained.

This application was provisionally approved and Members commented that the research project used a well established approach and agreed that consent was not feasible. This approval was subject to the following condition of approval:

- The information custodian should be amended to reflect a Head of Department and full details of the appropriate person are to be provided to the NIGB Office.

Action: NIGB Office to notify applicant of Committee decision.

g) ECC 5-07(g)/2009 Attribution Data Set Requirements from the Personal Demographics Service (2009)

The Department of Health required section 251 support to obtain an accurate count and demographic characteristics of the number of patients registered with each GP practice as the main base for funding allocations to Primary Care Trusts (PCT) and also for indicative budgets for GP practice under practice based commissioning. Access was required to information for patients registered with every GP practice in England and Wales on a specific day. In line with the current approvals process, approval under section 251 was required from the ECC in order to gain access to the personal demographics service (PDS) for this purpose.

The Committee noted the purpose of this application was the subject of a previously approved application [ECC 2-06(h)/2009]; however, the source of the data differed. Members agreed that there was sufficient justification for the data and that it fell within a medical purpose as specified in the Health Service (Control of Patient Information) Regulations 2002.

Members also noted that it appeared that the GP Market Share Analysis which involved the calculation of distances of patients to GP Practices, previously the subject of a different application [ECC 2-06(i)/2009], had been incorporated into this application. However, as the same security arrangements were in place and the applying organisation remained the same, Members agreed, in this instance, that this would be satisfactory.

This application was provisionally approved, subject to the following condition of approval.

1. As the application constituted the same approved activity as per reference ECC 2-06(h)/2009, the same condition of approval was applied to this application;

   The annual review, to be submitted no later than 12 months from this date of approval, must provide details of the solution, and progress, in establishing appropriate patient involvement and appropriate dissemination of patient information, taking into account that utilising one medium such as websites was unlikely to be sufficient.

Action: NIGB Office to notify applicant of Committee decision.

h) ECC 5-07(h)/2009 ECC 5-07(i)/2009 Descriptive evaluation of the high security DSPD pilot services

This application from Imperial College sought section 251 support for an existing study, for a period of five years, for the purposes of a descriptive unmatched case control study to evaluate the treatment of high risk offenders. Support was requested to collect outcome, demographic, psychological, clinical, offending and risk management data on offenders with DSPD within high security units.

Members noted that this was an existing study and welcomed the fact that section 251 was being sought. Members considered this application in detail and concurred that the overall purpose fell within the definition of medical purposes as specified in the Health Service (Control of Patient Information) Regulations 2002.

Members assessed the reasons given for not seeking consent and noted that a strong case had been made. It was agreed, in the specific circumstances of this application, that consent would not be feasible and that the nature of offenders in high security units would make the seeking of valid consent extremely difficult. Members highlighted that the cohort would be a mobile group for security purposes and therefore there would be a need to link the data and that the information would be required from a secondary source.

Members agreed that due to the nature of the cohort, there was a strong public interest in this activity being undertaken and in providing support to this application the lifting of the duty of confidentiality would be appropriate.

Members also emphasised that section 251 support was only in relation to high secure units. Should the study be carried out in medium secure units (MSU), or if the members of the cohort were transferred to medium secure units, then a new application would need to be submitted to the Committee. Any new application covering MSUs should take fully into account the nature of this specific cohort, and the Committee wished to highlight that support had been given to this application due to the strong public interest the treatment of offenders in high secure units.

Members provisionally approved this application subject to the following conditions:

1. Provision of a favourable opinion from a research ethics committee covering the scope of this application prior to formal approval being provided.

2. That any further intentions to carry out the study within medium secure units should be the subject of a new application and were excluded from this approval.

Action: NIGB Office to notify applicant of Committee decision.

i) ECC 5-07(i)/2009 Closing the gap between evidence and practice in primary care: the testing of review criteria to selected NICE guidelines

This application from Newcastle University required section 251 in order to access GP records to extract pseudonymised information to measure adherence of healthcare professionals to selected NICE guidelines in primary care in the NHS South of Tyne and Wear.

Members were mindful that in particular, depression is a highly sensitive area and therefore strong justification would be required to provide section 251 support to access records related to this condition.

Members noted that identification of the cohort would initially be carried out by practice managers at each of the surgeries, and did not consider that sufficient justification had been provided to explain why these practice managers could not carry out the extraction.

Members were also concerned by the implication in the response to question 5 where section 251 support would effectively be used to override patient dissent. A core principle of section 251 was that it should not be used to override patient dissent. Members considered the numbers to be relatively small at each practice, and therefore concluded it would be feasible for either the practice managers to extract the information, or for the practice managers to actively seek consent on behalf of the researcher for the researcher to access the information.

Members also considered the public interest in this activity, and whilst agreeing that it was an important activity, did not feel that it was sufficiently in the public interest to justify the temporary lifting of the common law duty of confidentiality.

The Committee were therefore unable to provide section 251 support to this application, and recommended that either a consent option be pursued, or that practice managers be asked to extract the anonymised data on the applicant's behalf.

Action: NIGB Office to inform applicant of Committee decision.

j) ECC 5-07(j)/2009 Transitions to Palliative Care for Older People in Acute Hospitals (Census in Care)

This study carried out by the University of Sheffield required section 251 in order to access patient records to carry out a case note review to identify patients with palliative care needs. The study aimed to assess needs and provision of palliative care in two hospitals and examine how transitions to palliative care were managed to identify best practice.

Members agreed that this was an important piece of work in the field of palliative care; however, on the basis of the details provided, Members considered that there were significant opportunities to obtain consent from the cohort. The Committee noted that the intention was to provide patient information leaflets to the cohort whilst on-site, and agreed that whilst giving the information there would be sufficient opportunity for ward staff to seek consent on behalf of the researcher. Members concluded that the cohort was small enough for consent to be feasible and that there would be plenty of opportunities to gain this.

A concern was raised that the application seemed to confuse consent from GP practices with consent from patients and wanted to clarify that consent needed to be gained directly from patients.

Members were also concerned that the application indicated that consent was not being sought in order to avoid patient dissent and Members emphasised that section 251 should not be used to override dissent. The Committee were mindful of the implications of the Mental Capacity Act and that consent should be sought in line with the Code of Practice, and therefore section 251 could not be used to avoid the implications of this Act.

Concerns were raised as it appeared the researchers wished to look through all patients' records who were present to identify a cohort for the second phase of the study. Member additionally queried Phase 1 of the study, which involved access to records without consent, and the specific question that it would address, and were not clear on how it would inform Phase 2 of the study.

Members were also of the view that census data typically used anonymised information.

The Committee were therefore unable to approve this application on the basis that there appeared to be ample opportunity to gain consent. Additionally Members commented that where there was opportunity to gain consent, section 251 should not be used to override possible dissent.

Action: NIGB Office to inform applicant of Committee decision.

k) ECC 5-07(k)/2009 Factors associated with Community Treatment Order (CTO) use

This application from the University of Leeds required section 251 to access clinical records in order to extract pseudonymised data to carry out a case control study to examine the demographic, clinical and healthcare variables of service users detained under section 3 of the Mental Health Act who were placed on CTO's. These would be compared with those service users detained but subsequently discharged from detention altogether.

Members assessed the purpose of this application and agreed that the issue under investigation was clinically relevant. Members also agreed that the current study design was retrospective which would make obtaining consent relatively difficult. Members also noted that extraction of the pseudonymised data items would involve access to identifiable data and that therefore an appropriate legal basis would be required to carry out the study. However, the Committee was mindful that section 251 could only be used as a last resort and were not persuaded in this instance that other options had been fully explored to justify the use of section 251.

As the cohort was noted to be relatively small the Members did not feel that significant justification had been provided for not gaining consent. They did not consider that staff training issues should be a barrier to gaining consent.

Concerns were also raised that there seemed to be some confusion within the application and crucially the applicant did not seem to class the mental health data they were collecting as sensitive.

Members discussed that the study could be reframed as an audit as it shared similar outcomes to those of an audit and due to one of the researchers' medical appointment in the

Trust, the Committee would regard the work as part of direct care provision. Within such circumstances implied consent would be considered reasonable and would therefore negate the need to seek section 251 support. Members concluded that if audit, it would be appropriate for the clinical teams in the Trust to carry out such an audit and therefore the applicant should consider liaising with the clinical director for mental health.

The Committee considered that the justification for section 251 support within the application was not sufficiently compelling to justify support under section 251. Members also agreed that an alternative approach would be for the medical records staff to extract the pseudonymised information on the researcher's behalf. The Committee appreciated that this might be difficult but reframing the activity as an audit project could mean that they would be more likely to assist.

The Committee did not approve this application on the basis that the activity could legitimately be carried out as an audit.

Action: NIGB Office to notify applicant of Committee decision.

l) ECC 5-07(l)/2009 Enhanced Recovery Programme

This application from the Department of Health was for a study that sought to identify the impact that an enhanced recovery model of care would have on both patients and the NHS organisation in order to understand which elements of the enhanced recovery process were being applied. Section 251 support was requested in order to access NHS Number, Name, date of birth and gender in order to link with HES (and PROMS data in approximately 18 months' time).

Members considered this application in some detail and agreed that it was an important piece of work, however, Members were unclear on the outcome the application set out to achieve and required clarity whether it was research, audit or service evaluation. The view was that the overall purpose of the study should be described in detail and that the application should include exactly what was being measured.

Members queried why consent could not be sought and on the basis of the application, felt that consent would be possible in some instances, and that this should be explored.

Members agreed that user involvement was not significantly developed and that it was inappropriate. Members queried the statement in section (p) where it stated that local Trusts would have their own patient and public involvement forums to draw upon. Members agreed that the responsibility would lie with the applying organisation to ensure there was sufficient user involvement and that if intending to devolve some of this responsibility to a local level, a mechanism should be put in place to manage this activity. Members stressed that the onus lay with the applicant to lead user involvement.

Members noted there was no mention of a control group and agreed that they would have expected some mention of this.

The Committee considered there to be a number of outstanding issues as set out above which meant that the application could not be approved. The Committee agreed that if these issues were adequately addressed, they would welcome a resubmission.

Action: NIGB Office to notify applicant of Committee decision.

m) ECC 5-07(m)/2009 United Kingdom Gynaecological Oncology Surgical Outcomes and Complications (UKGOSOC)

This study by University College London Hospitals (UCLH) sought to prospectively audit, over a 6-8 month period, major surgical procedures undertaken in participating Gynaecological Oncology centres in the UK. They sought to use these outcomes in order to establish standards for future bench marking and national audit. Section 251 support was requested for the University College London Hospital's database administrator, on an initial and ad hoc basis, to have access to the database hosted by Trent Cancer Registry for the purposes of testing and administering the system, which would by default involve access to identifiable data.

Members were sympathetic to the purpose of this application. They noted that the collected data would be entered on the system by authorised users at the participating Trusts, and that the database would be hosted by Trent Cancer Registry. It was noted that it would be likely that the audit team at UCH/UCLH would generally only have access to pseudonymised data but it may be possible that they would have access to identifiable fields. Members noted that the database administrator would have access to the whole dataset as this role resource would not be provided by the Cancer Registry.

Members discussed whether suitable access controls could not be placed within the system to avoid the audit team having access to identifiers if consent was not obtained and queried why the database administrator resource could not be provided by the Cancer Registry as they hosted the database.

Members also agreed that the reasons for not consenting had not been significantly addressed within the application and queried why this could not be obtained at a local level. They agreed that it would not be appropriate for the audit team to have access to identifiable data without consent and that as the database was hosted by the Cancer Registry, it was not appropriate for section 251 support to be provided to the database administrator.

The Committee were unable to provide section 251 support to this application as they considered that consent at local level would be feasible. Additionally the Committee reiterated that section 251 was not to be used to overcome administrative inconvenience and that it would not be appropriate to use section 251 to cover one person.

Action: NIGB Office to notify applicant of Committee decision.

n) ECC 5-07(n)/2009 Audit of recording of Ethnicity in BLPT Service Users

This application from Cambridgeshire and Peterborough NHS Foundation Trust requested section 251 support to extract data from medical records to examine the extent to which the ethnicity of mental health service users in Bedfordshire and Luton was recorded in individual case notes.

The issue discussed was whether the applicant was a member of the clinical care team. There had been some inconsistency within the application which meant the status of the applicant was not clear. The Committee agreed that if the applicant was a member of the clinical care team that the activity would be an essential part of local clinical audit and should be carried out routinely, and therefore section 251 would not be required.

The Office would seek clarification from the applicant and advise on the Committee's decision that is part of the clinical care team that section 251 support would not be required to carry out the activity.

Action: NIGB Office to notify applicant of Committee decision.

8. British Artificial Nutrition Survey (BANS) advice request – section 251 exit strategy

This letter was submitted to the Ethics and Confidentiality Committee with a request for an informal view on the BANS proposed exit strategy of pseudonymisation. In their last annual review Members had indicated that support would be provided for a further twelve months, but Members were concerned that it appeared that consent could be sought from sub-cohorts and therefore this should be fully explored in the next annual review in order to enable support to continue.

Members were informed that BANS had since met with the NIGB Office. This meeting explored the feasibility of pseudonymisation as an exit strategy and it was suggested that a view be put to the Committee in order to gain an informal view on the approach prior to formal submission of the annual review.

Members were supportive of the exit strategy proposed within the application and agreed, in principle, that the move towards pseudonymisation would be appropriate, primarily because of the decline in data submission.

Action: NIGB Office to inform BANS of Committee advice.

Secondary Uses Service Annual Review

This paper had been submitted to the July meeting, however there were some outstanding issues that the Committee were requested to consider and confirm. The Committee had agreed it was appropriate to anonymise the whole episode of sexual health data in the July meeting, including that within a secondary diagnosis. Members were asked to confirm this position and consider proposals about how this could be achieved.

Members agreed that confidentiality within the fields of sexual and mental health were particularly important and for that reason de-identification of data would be necessary. It was recognised that sexual health data was protected within regulations but that mental health data was not.

Members were informed that SUS currently relied on Trusts providing the information to de-identify data before it reached them; therefore they sometimes received identifiable data from Trusts. Members felt that this responsibility should not lie with the Trusts but instead a system should be in place whereby SUS cannot accept identifiers. It was discussed that ethical issues should not be set aside due to practicality issues and that, in regard to sexual health data, the Committee could not approve something that went against current legal regulations. Members were supportive of the proposal put forward by SUS to develop the current systems so that identifiers could be rejected before sending from the providers and agreed that this was the best way to proceed.

In conclusion the Committee felt that the whole episode should be anonymised and that a system should be developed to enable them to remain within the established legal requirements

Sexual and Reproductive Health Activity data set

The Department of Health Sexual Health Team had made a submission to the Information Standards Board (ISB) to obtain approval for a revised data set for central return to the NHS Information Centre. The current data set involved reporting of aggregated data. The new data set would involve reporting of patient level data to monitor delivery of reproductive and sexual health services including public health interventions in relation to access to services and quality of services. The Committee were asked to consider the proposed changes as they would relate directly to other decisions made by the ECC.

Members discussed whether the data collection proposed would be identifiable. They concluded that because this data was being collected by the NHS IC, there was a significant risk of identification because of the other data held by the IC e.g. within HES.

The Committee were concerned that the current proposals appeared to be breaching a number of current legal requirements, for example, the Venereal Disease Regulations and the Abortion Act. Additionally the Committee re-affirmed its principle that all sexual health data was particularly sensitive and therefore that all such data should be effectively de-identified to be included within SUS or other centrally held databases.

Members discussed that the data would be collected for a number of different purposes and that these needed to be separated out as different levels of data were likely to be needed for different purposes and that some would need to be satisfied with aggregate data in order to meet legal requirements.

Members acknowledged the importance of work in relation to the prevention of teenage pregnancy; however they did not feel that a case had been made for why this information was needed in the current proposed form. Members felt this could be undertaken with secure linkage processes and then handled in an aggregate way in terms of central reporting.

Members queried why the public health analyses were not being undertaken by the Health Protection Agency (HPA) as they already had a statutory basis to obtain this information and have developed very secure processes and procedures in relation to Genitourinary Medicine Clinic Activity Data Set (GUMCAD) which could be used for other similar data and analyses.

The documentation seemed to indicate that this was activity data rather than diagnostic coding, however, activity codes could be disclosive of confidential /restricted information and there are issues about ICD10 codes which are both activity and diagnostic which would also need to be considered and managed.

In conclusion Members agreed that further consideration needed to be given to separating out the different purposes and data requirements for each before considering whether or not identifiable data was really necessary for a particular purpose and what the legal requirements were in relation to both restrictions and reporting.

Note from Secretariat: Following clarification from applicant after the meeting this application was subsequently reviewed by DMsG which concluded that the data collected was not identifiable and would not require section 251 support. DMsG noted that the intention of the applicant was to develop an integrated SRHAD / GUMCAD data stream and requested to be kept informed of this to ensure that the data remained anonymous should the data be linked with other datasets in future.

9. Any other Business

No further business was discussed.