Meeting held on Tuesday 24 November 2009

Present

Members: Professor Dame Joan Higgins (Chair), Mrs Pauline Brown, Dr Tony Calland, Professor Mike Catchpole, Dr Patrick Coyle, Professor Carol Dezateux, Dr Fiona Douglas, Ms Stephanie Ellis (*arrived at agenda item: ECC 6-06(k)/2009*), Professor Sir Denis Pereira Gray, Mr Michael Hake, Ms Sue Parroy, Dr Mark Taylor, Mr Terence Wiseman.

In attendance: Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Approvals Officer),* Mr Paul Eveson *(Department of Health),* Dr Andrew Harris *(ECC Chair Elect),* Ms Melanie Kingston *(Deputy Approvals Manager),* Mr Andrew Lall *(Deputy Approvals Manager),* Ms Zoë Lawrence *(NIGB Business Manager),* Ms Karen Thomson *(NIGB IG Lead)*.

1. Welcome and apologies for absence

Apologies for absence were received from Dr Tricia Cresswell, Ms Ros Levenson and Professor Roy McClelland.

The Chair welcomed Dr Andrew Harris, who had been appointed Chair of the Committee from 01 January 2010, to the meeting. Dr Harris was attending this meeting as an observer. The Chair also welcomed Mr Andrew Lall, a new member of the secretariat, to the meeting.

2. Minutes of last meeting [ECC 5-02/2009]

Minutes of the last meeting held on 21 September were approved, subject to minor amendments.

Members received an update on the Sexual and Reproductive Health Activity data set. Following clarification from the applicant, the application was subsequently reviewed by DMsG which concluded that the data was not identifiable and would not require s251 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 it be linked with other datasets in future. It was agreed that the previous minutes would include this addition.

NIGB Office Report [ECC 6-02(a)/2009]

<u>Update on revisions to the Regulations</u>

Members were informed that Mr Phil Walker (Deputy Director Information Governance Policy, Department of Health) had submitted a briefing to Mr Alan Perkins (Director of Policy and Planning, Informatics Directorate, Department of Health) on potential revisions to the regulations with a view to this being considered subsequently by Ms Christine Connolly (Chief Information Officer for Health). A response was pending and Mr Walker had indicated that it was unlikely that new Regulations would be brought to Parliament in 2010.

Consultation – HFEA disclosure of identifiable information for research

Ms Karen Thomson notified the Committee of a Department of Health consultation on the Human Fertilisation and Embryology Act 1990 – disclosure of identifying information for research that would close on 2 December 2009. Members were informed that a draft response would be circulated outside the Committee for comments.

ECC Appeals

Members were informed that the NIGB received an appeal on 1 October 2009 regarding the outcome to an application [ECC 4-15 (j) /2009] that was rejected by the Committee in July. The NIGB appeal panel upheld the decision of the ECC. The NIGB had now received two appeals and in both instances the original decision of the ECC had been upheld.

External meeting – Office of National Statistics (ONS)

Members were informed that the NIGB Office had met with ONS on 20 October 2009 to discuss strategic and operational issues between the two organisations when approving applications and releasing data. It had been agreed that a memorandum of understanding (similar to the one developed with the HFEA) would be drafted for the ECC to approve.

External Meeting - National Screening Programme: Fetal Anomaly

The NIGB Office met with the National Programme Director at the National Screening Programme for Fetal Anomaly. The purpose of the meeting was to discuss the National Screening Programme's role in monitoring and quality assurance when using patient information. The quality assurance system received non-identifiable data from screening laboratories. The Screening Programme had requested access to outcome data to be linked with the scanning data as part of this quality assurance process. It was agreed that as they did not seek to obtain outcome data retrospectively, and requested this data on a prospective basis, and as they would be carrying out a full consent process, that section 251 would not be required.

External Meeting – Centre for Maternal and Child Enquires (CMACE)

A meeting took place with a representative from the Confidential Enquiry into Maternal and Child Health (CEMACH) in order to discuss a number of changes. CEMACH had now been renamed CMACE is a registered charity, requiring a review of the organisational governance structure. The work was still funded by the National Patient Safety Agency (NPSA). They would also be moving to annual surveillance reporting rather than the previous three-yearly. They had been asked to conduct local audits on behalf of Trusts, and although previously agreed by PIAG that local clinical audit following the care pathway could be undertaken without further approval under section 251, this was on the basis that the organisation undertaking the audit would be one of those involved in the delivery of care to the patient. Although the use of CMACE as a third party data processor would be reasonable as their expertise would add value to the audit, it would breach confidentiality and therefore approval would be required to carry this out. It was agreed that the best approach would be to provide a new application rather than encompassing this activity within the current approvals.

Training sessions

The NIGB Office recently presented a session on section 251 and research applications to a group of approximately 90 information governance health and social care practitioners. The event was organised by Dilys Jones and the feedback received was positive.

The Office, following an invitation from Mark Taylor, delivered a workshop session on 'health research & consent for consent' at the University of Sheffield, which had been well-received.

Member expenses

Members had received notification informing them that the allowance that could be claimed for each meeting had increased to £175 for ECC members and to £220 for the Chair. The difference in amounts could be claimed back retrospectively for meetings from June 2008.

Away Day

The ECC Awayday held on 25 September 2009 was reported as very successful in tackling a number of key issues that had arisen from applications. The Chair thanked all those who had prepared papers for the meeting and who took part in the discussions. A list of action points from the away day had been prepared and progress would be reported at the February Committee meeting.

NIGB Public Meeting

The NIGB Public Meeting was held on 12 November at Westminster Central Hall, Storey's Gate. The NIGB Annual Report (which included a section on the work of the ECC) was launched at the meeting.

Social Care Record Guarantee

Members were informed that the Social Care Record Guarantee had been launched to social care and health professionals during week commencing 19 October at the Social Care Conference in Harrogate and through other media. It explained to service users how the information they provided to social care staff would be used and what control they could have over this. It was based on law, best practice and professional guidelines; complemented the NHS Care Record Guarantee and supported information sharing between health and social care. The Guarantee was launched to the public and service users at the NIGB public meeting.

DMsG

The Terms of Reference for the DMsG had been published on the NIGB website.

Staffing update

Members were informed that Mr Andrew Lall had been appointed as Deputy Approvals Manager to the NIGB Office. His primary role would be to support the application process and to provide secretariat support to the ECC. Following another open recruitment process, Claire Edgeworth had been appointed as Approvals Officer. She had been filling the role temporarily following Melanie Kingston's promotion to Deputy Approvals Manager.

NATCANSAT Applications – Change of Data Custodian

Members were informed that Ms Helen Forbes would now act as data custodian for all NATCANSAT approved datasets, listed below:

1. PIAG 3-09(g)/2003 Radiation Treatment Dataset
2. PIAG 1-07(p)/2004 Cancer Registries/HES Analysis of cancer registration data to inform cancer service guidance development
3. PIAG 2-07(r)/2004 Analysis of patients receiving palliative care
4. PIAG 3-09(h)/2003 HES/NSTS Cancer Service Guidance
5. PIAG 4-09(g)/2003 HES/NSTS Analysis of variations in coronary heart disease Provision
6. PIAG 1-05(d)/2006 NW SHA Data Warehouse – patient travel times analysis

Extensions

PIAG 1-05 (c)/2007 Linkage of National Cancer Registry data to national HES data - extension request

The original application covered all England patients diagnosed with Cancer aged 0-99 during 1971 – 2006. More data was now available, including National Cancer Registry data for patients diagnosed up to 2007, with follow-up to 2008, and HES data up to 2008. The extension request covered all England patients diagnosed with Cancer aged 0-99 during 1971 – 2007 with follow-up to 2008. This was approved by Chair's action.

PIAG 4-08(b)/2003 NCEPOD

The National Confidential Enquiry into Patient Outcomes and Death (NCEPOD) submitted three new studies for approval. These were the Parenteral Nutrition Study, Peri-Operative Care Study and Elective and Emergency Surgery in the Elderly. They all followed the same methodology outlined within the original application and subsequent annual reports. The studies were approved via Chair's action.

ECC 2-06(d)/2009 Risk adjustment in Neurocritical Care (RAIN)

This extension was approved by way of Chair's action and the study now had permission to collect Hospital Number. It was noted that collecting Hospital Number would not significantly increase the identifiability of data already collected.

Amendment to ISRAS Study (Improving Stroke Recognition by Ambulance Services – Use of the ROSIER Assessment Tool) 2-06(m)/2009

The main aspects of the amendment were:

1. That there would be three copies of the ROSIER proforma and it would be in an identifiable format.
2. A Stroke Research Practitioner, provided by the Stroke Research Network, would now consent some patients. They would be a member of the stroke clinical care team.

As section 251 support had already been given for the study, and there was no extra disclosure of information outside the clinical care team, the amendment was approved by Chair's action.

ECC Chair's Report [ECC 6-02(b)/2009]

Report from NIGB meeting 28 October 2009

Members were informed that the Board accepted the recommendations the ECC proposed in relation to:

1. Providing a response to the Wellcome Trust Report, '*Towards Consensus for Best Practice'*
2. The need to fund the recruitment to trials and research projects in Primary Care
3. The development of guidelines for 'secondary permissions' to access research databases.

The NIGB discussed a number of other items, including the Research Capability Pilot Projects, patient access to electronic health records and the Care Quality Commission's recent report on the management of personal data by healthcare organisations.

Appointment of new members to the ECC

When the ECC was established in January 2009, PIAG members were offered new appointments to the Committee on a rolling basis. Dr Fiona Douglas's term of office was due to end in December 2009 and the post had been externally advertised. There was a strong field of candidates and interviews were held on 23 October 2009, with a panel which included an external assessor. Dr Fiona Douglas had been successful in her application to continue as a member of the ECC and had been appointed for a further 3 years.

Thank you

Following 8 years as Chair of the Patient Information Advisory Group (PIAG)/ ECC, Professor Dame Joan Higgins recorded her thanks to the members of the Committee who had been involved since 2001 and the secretariat. Dame Joan would be ending her chairmanship of the ECC on 31 December. She said what an honour it had been to work with such a principled and knowledgeable group of people, who worked so hard to raise ethical standards in research, to promote good consent practice and to ensure that patients' interests were promoted and enhanced.

DMsG (Database Monitoring sub-Group) Report [ECC 6-02(c)/2009]

The DMsG Chair presented a written report on the status of applications and approvals.

Applications for HES data

041109-06-a Oxford University, Unit of Healthcare Epidemiology (UCHE)

041109-06-b Cancer Research UK at Oxford University, Million Women Study

041109-06-c National Centre for Social Research

MRIS applications

MR1171 – Getting out of the house study

3. Dr Foster Annual Review [ECC 6-03/2009]

Members reviewed the annual report from Dr Foster Unit in relation to application PIAG 2-05(d)/2007 in addition to an appendix which contained a list of the data fields supplied to Dr Foster Intelligence (DFI). DFI did not have permission to receive identifiable data and the Committee were asked to consider whether they were satisfied that the data provided to DFI was effectively anonymous.

Members queried if any other NHS data would be received by DFI and whether the data received through the application could potentially be linked to this. Members also queried the use of postcode data by DFI and when this would be destroyed.

The Committee requested clarification over the following before the annual review could be approved:

1. Whether NHS data was received by DFI from other data sources that could be linked with data provided as part of the application. The Committee were concerned that there was a small possibility that this could occur and therefore requested reassurance over the matter.

2. Members requested clarification over the plan for reducing identifiability once derived area level indices have been obtained. Members were of the understanding that these are stripped out at 3 yearly periods, however, it was queried whether this could be carried out at an earlier stage.

Action: NIGB Office to follow up queries with applicant

4. Annual Review – ASCEND 4-09(h)/2003

This application from the Clinical Trials Service Unit (CTSU) was originally approved in 2003 by the PIAG. In considering the annual review, Members assessed the original application, anonymised correspondence received relating to ASCEND and the annual review documents provided to the Committee.

The Committee were informed that issues had been raised by Welsh GPs to the British Medical Association in Wales and that there had been correspondence with the NIGB regarding this matter. GPs had received letters informing them that their patients would be approached and that this had been approved by PIAG, and there had been concern that their permission had not been sought. GPs had also expressed concern about patient confidentiality and therefore required clarification over the approval. In particular, it was queried why the cohort could not be asked for consent during their annual visit to the diabetic retinopathy service. CTSU had been asked to address, in their annual review report, the feasibility of following this approach. The Committee also queried where the consent letters were being sent from, as complaints that had been received had suggested that the letters had been sent on CTSU headed paper.

A number of patient complaints had also been received querying how the CTSU had been able to access their contact details and that they had been contacted directly by the CTSU and not via a known clinician.

Members were asked to consider what, if any, actions should be taken and whether they were satisfied with the use of section 251 within this study.

Members discussed the methodology outlined in the annual review letter and noted that the majority of potentially eligible patients were identified from centrally held registers. It was noted that the clinician responsible for the respective register allowed the CTSU at the University of Oxford to process the contact details of the cohort under section 251.

In particular, Members noted that, before invitation letters are sent, the GP would be given the opportunity to indicate whether or not particular patients should be invited to participate. Once this stage was completed then the invitations were sent in the name of the local clinician to potentially eligible patients. Members were of the view that there had been some ambiguity arising from the original application and in particular, the outcome letter which stated:

“That the applicants confirm that initial contact with patients to obtain their consent will be via a clinician known to them (e.g. their GP or the consultant responsible for their care)”.

Members discussed that there appeared to have been some confusion about the practical meaning of this condition of approval. In the interests of clarity, the Committee felt that it was necessary to emphasise the original condition of approval that the approach for consent should be made by a clinician known to the potentially eligible patients. This should be via their GP, treating clinician or diabetic nurse. Members noted that currently the invitation letter was sent on CTSU headed paper which also included a covering letter from the relevant practice, and that the applicant was aware of a number of circumstances where this covering letter had not been included, which therefore conveyed the impression that the letter had been sent directly from CTSU. Members were concerned at this perception and agreed that the invitation letter should be on practice headed paper. Members also agreed that invitation letters should be addressed to named individuals and not simply to an address (which had been the basis of one of the complaints from a patient).

With these caveats, the ASCEND study annual review was approved subject to the following conditions:

1. The invitation letter must be sent to each member of the cohort from a clinician known to them (e.g. GP, treating clinician, diabetic nurse).

2. The invitation letter must be on practice headed paper, and not on CTSU headed paper.

3. Letters must be addressed to named individuals.

4. Where patients were in regular contact with the service, they must be asked for consent to participate.

The Committee was keen to support the work of ASCEND and agreed that this was an important study and noted that previous annual reviews had demonstrated a productive method of developing processes around seeking consent. Members also noted, over the lifetime of the study, that the number of complaints received had been small. However, it was necessary to ensure that section 251 support was being utilised within the terms of the approval. The Committee recommended that a meeting should be included as part of the annual review process.

The Committee also recommended that, in future, when a specific condition of approval relates to who the invitation letter should come from, the researcher should confirm with the NIGB Office who will make the initial approach to the patient to ensure clarity.

Action: **NIGB Office to inform applicant of Committee decision.**
NIGB Office to schedule annual review meeting and report back outcomes to the Committee.
NIGB Office to ensure future applicants confirm identity of person making initial approach for consent.

5. Resubmitted applications for section 251 support

a) Secondary Uses Service (SUS) [PIAG 2-05 (b)/2007]

This resubmitted application from SUS arose from the annual review of the 2007 application which was submitted to the ECC at its meeting in September 2009. At that meeting, Members noted that there appeared to be a number of new activities which had not been included in the original application, and had therefore requested that a new application be submitted, clearly setting out the purposes and activities of SUS. It was reported that meetings had taken place with the NIGB Office and Members in the interim period in order to aid clarification of the application.

The Committee noted that a significant amount of work had been carried out to define the purposes and activities of SUS and it welcomed the improved clarity of the application. Members noted that the information would remain within the 'NHS family' and that access appeared to be robustly managed. Members noted the plans for moving towards Specific Regulations, and welcomed and encouraged this. Members agreed that consent may not be a reasonably practicable option and that efforts made to pseudonymise the information and maintain effective access controls were reassuring.

A query was raised over whether it would be feasible for SUS to move towards using pseudonymised data at source, as the Committee had been concerned over the extent of identifiable data flowing into SUS, which would subsequently be pseudonymised. Members who had attended meetings with SUS informed the Committee that currently those running the system had access to identifiers in the form of 'clear data' for the purposes of cleaning and anonymising. Members noted that data received was coded and would therefore make identification difficult. Members queried whether timescales could be introduced to monitor progress towards pseudonymisation. However, as NHS number was still not used throughout the NHS, it was considered to be unfair to impose timescales because use of NHS number was outside the control of SUS.

The Committee's deliberations focused upon the purposes set out in section (b) of the application:

1. Commissioning Data Sets (CDS)

Members noted that this aspect had been included within previous applications, but precise clarification over approval status was required. Section 251 approval was requested to enable the disclosure of patient identifiable data from care providers to the Department of Health (DH) (in the form of SUS) and disclosure from the DH to the NHS commissioning bodies, through allowing the extraction of CDS based data from SUS to proceed. It was noted that CDS stored in SUS underpinned the NHS commissioning process (including practice based commissioning, payment by results and the 18 week referral to treatment and the planning of services including performance management).

The Committee approved this activity.

2. Use of Mental Health Minimum Data Set (MHMDS)

Members noted that this was a new aspect to the 2007 application. Section 251 support was requested to enable the disclosure of patient identifiable data from mental health care providers to the Department of Health (DH) (in the form of SUS) and disclosure from the DH to the NHS commissioning bodies, through allowing the extraction of MHMDS based data from SUS to proceed. It was noted that access to data would be controlled via Role Based Access Control, and that identifiable data would be available to providers and commissioners only for the patients for whom they are responsible.

This purpose was provisionally approved subject to clarification of the following. It appeared to Members that use of mental health data did not appear to be handled in the same way as sexual health data, in terms of inbound assurance, and whilst acknowledging that there are specific legal constraints over sexual health, queried this discrepancy and requested whether the same inbound assurance could apply to mental health data.

3. Data Quality uses of Personal Demographic Service (PDS) data

Members noted this was a new aspect to the original 2007 application and that section 251 support was sought to allow disclosure of patient demographic data from PDS to SUS, and for the storage and disclosure of PDS sourced demographic data from SUS. The onward disclosure would be to NHS users of SUS in supporting data quality activity within SUS, and to the PDS Back Office to support data quality work in the main PDS system.

This activity was provisionally approved, subject to applicant clarification on whether reporting would disclose any identifiers.

4. Use of Data from Choose and Book (CAB)

Members noted that this was a new aspect from the previous 2007 application. This purpose sought section 251 approval for disclosure of data from CAB to SUS and the use of CAB sourced patient administrative data in SUS to support the development of patient pathways and associated Referral to Treatment Time (RTT) monitoring.

Members agreed that this was a reasonable activity and approved this activity.

5. Sensitive clinical data – inbound assurance

Section 251 support was requested to clarify diagnosis and treatment codes that require anonymisation of records across GUM (Genito-Urinary Medicine)/HIV and sexually transmitted diseases, along with mechanisms to identify relevant records so that anonymisation could take place within SUS. In particular, the application should provide section 251 support to:

- the inbound assurance facilities developed for dealing with sensitive clinical data in relation to Human Embryology, HIV and Sexually Transmitted Diseases

- the publication of a Data Set Change Notice (DSCN) to provide a definitive list of codes covering the spectrum of GUM/HIV /Sexually Transmitted Diseases

- the introduction of the NHS Number Status Indicator field value of 90 within the same DSCN in order to enforce the removal of all patient-identifiable information from the CDS record at the point of submission and before receipt by SUS.

These activities were approved.

6. Commissioning GUM services

Members noted that this was a new aspect to the application and the reason given for this request was that it was not currently feasible to actively commission GUM services, as there are no means to link GUM activity to the patients PCT. Approval was sought for the flow of Patient Pathway Identifier (PPI), Organisation Code of PPI Issuer and post-code from GUM service providers to SUS without disclosure of the data items and to permit the use of the data items in pseudonymised form.

Members were of the view that it was important for patients to be fully anonymous when accessing these services. They also discussed the requirement to maximise efficient usage of the NHS but, on balance, felt that anonymity should be preserved.

Members queried whether full postcode was required to check correct allocations to services. Members were of the view that partial postcode would be adequate for payment by results and commissioning purposes, and therefore if full postcode was required, then a significant justification would be required.

This aspect was not approved.

7. Welsh residents treated in England (approved, pending clarification)

Members noted that this formed part of the existing 2007 approval, and that a request to extend the data sets was included in this updated version. Section 251 support was sought to support the flows of Out Patient (OP) and Accident and Emergency (A&E) and Admitted Patient Care (APC) data derived from CDS in identifiable form relating to Welsh Residents from SUS to the Welsh Office.

The Committee approved this aspect, subject to clarification that disclosure should be made to the Welsh Assembly Government rather than the Welsh Office

8. Changes to SUS pseudonymisation process

The pseudonymisation process had originally been presented to the Security and Confidentiality Advisory Group during the initial development of SUS in 2004. The changes were outlined in the briefing paper to this application and the Committee noted this change.

In conclusion, Members welcomed the clarity of the revised application and agreed that section 251 support could be provided for a period of one year, and a new application would be submitted to the Committee's meeting in December 2010 if Regulations were not in place by then. It was noted that should there be any changes to SUS in the interim period that the applicant should contact the NIGB Office.

Action: NIGB Office to notify applicant of outcome.

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

This application was originally considered at the September 2009 Committee meeting, and due to a number of areas requiring clarification that had not been adequately addressed, the

Committee requested that the application be resubmitted to its November meeting. A meeting took place with the NIGB Office in the intervening period in order to discuss the outcome letter and to provide further clarification.

The Committee considered the revised application and agreed that, while some aspects appeared clearer, some clarification was still required over a number of fundamental areas.

Members were not persuaded that a clear justification had been provided for use of full name. They noted that it appeared to be so that the clinician could identify and remember patients but advised that this was not sufficient justification. They were also concerned about the lack of meaningful patient involvement.

There was concern about the relatively limited opt-out requirement. Members queried the permanent retention of identifiers and wanted to understand the circumstances to justify this. Members felt that it would be particularly hard to justify retaining information on those who had not consented to donation as there would be no apparent reason for this.

Members also felt there could be greater clarity over the research objectives and were of the view that some aspects constituted an audit of clinical services which could potentially use anonymised data or be carried out locally. Members also noted that the applicants said that ethnicity would be identified by looking at the name of the individual and this was considered to be an unreliable method. Additionally the Committee felt that ethnicity data could be obtained if sufficient justification was made.

Members discussed the matching of data with ACORN, a market research database, but agreed that this idea was sound even though there could be another method of achieving this objective.

The Committee agreed that this was an important activity and the outcomes would be of significant benefit to the general public. However due to significant reservations the Committee felt that they could not approve this application. The Chair queried whether it would be beneficial to the applicant to meet with Members of the Committee in order to clarify and reformulate the application. Professor Carol Dezateux and Mr Terence Wiseman agreed to liaise with the NIGB Office in order to arrange a meeting with the applicant.

Action: NIGB Office to inform applicant of Committee decision
Action: NIGB Office to arrange a meeting between applicant and Committee Members.

6. New applications for section 251 Support

(a) Evaluation of preterm images (ePrime) [ECC 6-06(a)/2009]

This application from Imperial College London required section 251 for a researcher to have access to the SEND database to screen and identify a cohort for participation (818 preterm babies who will be referred to a specialist centre to have both ultrasound and MRI scans). Once identified, subsequent consent to participate would be sought by a member of the cohort's clinical team.

The Committee considered this to be a clear and well-presented application and the subject matter of benefit and importance due to the high frequency of neurodevelopmental impairment in preterm infants. Members agreed that user involvement was good and as a whole, that it was a well-developed study and that the model described was robustly presented.

Members queried on what basis the SEND database currently held identifiable information. If it was consented then there may be an opportunity for consent to be sought for this study.

It was felt that the application had not explored other methods of carrying out the initial identification of the cohort and Members queried whether this could be carried out by the database manager on behalf of the applicant. Members felt that alternatives should be considered before granting section 251.

Although Members required some clarification, on balance they felt that the study was important and therefore requested clarification over the following areas before determining whether approval could be provided.

Request for clarification:

1. It was not clear to the Committee on what legal basis the SEND database was currently operating and whether there was pre-existing consent for data to be entered on the database .
2. Members queried the identity of the data manager of SEND as referred to within the application and whether the applicant had considered the feasibility of the data manager running the query and identifying the cohort on their behalf. Local clinicians might then seek consent for the researcher to access their information via SEND.

If satisfied with the clarification of these issues, the final approval would be subject to the following conditions:

Conditions of approval

1. Provision of a completed system level security policy

2. A copy of the favourable REC opinion to be provided to the NIGB Office.

3. That consent from the cohort would be sought only by a member of the patient's direct clinical care team.

Action: NIGB Office to inform applicant of Committee decision

(b) Validation of risk assessments for patients from MSS (VoRAMSS) [ECC 6-06 (b)/2009]

This application from the University of Manchester required access at 6 and 12 months to patient medical records relating to a cohort of 560 patients who had been diagnosed with Schizophrenia across 38 medium secure units. This data would be linked with data held on the Police National Computer. The purpose of the study aimed to validate and assess the reliability and practical utility of risk assessment tools and guidelines for use in mental health services.

The Committee noted that the research team were closely linked to the National Confidential Inquiry into Homicide and Suicide, and agreed that the proposal was comprehensive and clearly put across.

Members noted one of the reasons for not seeking consent given in the application was that a previous study had demonstrated dissent. This study had sought reasons for dissent and the cohort had indicated that they would not wish to be interviewed but that, provided there was no

face to face contact with researchers, they would be content to participate. In light of this, Members agreed that support under section 251 could only be given if a robust trial of consent was carried out in parallel to the study. Members discussed that the consent model should be trialled so that the dignity and autonomy of the patients would be respected, rather than overriding dissent.

Members noted that consent was to be sought from healthcare professionals to release relevant healthcare information. The view was that it would be better if patient consent for sharing of information could be made at a local level and methods for introducing this should be explored.

Members agreed that the research evidence arising from this work would be likely to contribute significantly to improved risk management, and that therefore the balance of the public interest fell in favour of providing section 251 support, provided that a consent model was piloted in parallel. It was concluded that section 251 could be given in this specific circumstance as the outcome of the research was to provide better instruments for risk assessment rather than direct reduction of offences.

The Committee provisionally approved the application subject to the following conditions:

1. Members noted the application indicated there would be plans to engage with service users. A detailed proposal or plan on service user/patient engagement should be provided to the NIGB Office with relevant timescales indicated.

2. This plan on user involvement should be implemented and fully reported against (including outcomes, numbers, impact, changes made etc.) in the annual review.

3. A consent approach with participants should be tested in some situations, and this should be carried out in parallel with this study in order to provide evidence for the view that participants did not wish to be involved in face to face research, and this should be reported in detail in the annual review.

4. A copy of the favourable opinion from the REC to be provided to the NIGB Office before approval could commence.

5. Section 251 would only cover NHS patient information and did not provide access to data held on the Police National Computer. Separate access arrangements to the PNC should be arranged by the applicant.

Action: NIGB Office to inform applicant of Committee decision

(c) Follow-up of First Episode Psychosis [ECC 6-06(c)/2009]

The University of London submitted an application for section 251 support to access medical records to trace a cohort in a previously completed study, in order to carry out a follow up study. The cohort consisted of patients who had experienced a first episode of psychosis who had been recruited and given consent to the study between 1996 and 2000. The study aimed to determine whether measures taken at first presentation with psychosis predicted adverse outcomes at 9 to 13 year follow up. This application sought access to medical records to identify last known GP in order to contact the cohort. If the patient was no longer in contact with services, ONS databases would be searched for contact details.

The Committee noted that all participants were informed about follow-up in the future and agreed that the only reliable method to locate the patients would be via their medical records. They considered this to be a clearly constructed application and that, due to the original consent provided, the approach to be taken was reasonable. The Committee did note that the study had been delayed for a significant period of time and queried the reason for this. It was noted that the applicant had been attempting to follow up the study since 2004.

Members discussed the intention of the researchers to access the Police National Computer and Offender Index and reiterated that access to these databases was not within the remit of the ECC, and that the applicant would need to arrange separate access to these outside of the section 251 remit.

The Committee were concerned that the current method did not take into account the proportion of non-responders which may arise and that clarification was needed about how these would be managed.

Members agreed that user involvement arrangements were comprehensive and noted the engagement with the local R & D Users group with whom the proposal had been discussed. If not already done so, it was recommended that the proposed contact arrangements should also be discussed with this Group. Members also noted that for those who are not contactable ONS data would be sought and the Committee agreed to this approach in this limited context.

On conclusion the Committee felt that this was an important study and that follow-up was reasonable in the manner proposed. The Committee requested that the applicant clarified the following points before provisional approval could be issued:

Request for clarification

1. Members queried how the applicant intended to deal with non-responders as there was potential for this to be a high proportion of participants.

2. It was noted from the REC letter dated 06 April 2009 that the study was intended to commence outside of the usual two year post REC approval period. The Committee required confirmation of when the study was intending to commence and the reason for the delay.

Conditions of approval

If satisfied with the clarifications, this provisional approval would be subject to the following conditions:

1. That section 251 approval only related to patient information generated in England and Wales.

2. Access to the Police National Computer and Offender Index fell outside the scope of s251 approval.

3. Access to naturalisation information (deportation and emigration) from ONS fell outside the scope of section 251, therefore the applicant would need to ensure they had the appropriate access to this information.

Action: NIGB Office to inform applicant of Committee decision

(d) Seascale Birth and Schools Cohort [ECC 6-06 (d)/2009]

This application from the University of Southampton aimed to carry out a long-term follow up (to 2009) of a cohort who had been born in the village of Seascale and those who had attended school there between 1950 and 1983. Information on deaths and cancer registration was requested and would be accessed via the Medical Research Information Service (MRIS). The study aimed to determine whether there had been a continuing health disadvantage to the cohort.

The Committee agreed that this was an extremely important study and provided a rare opportunity to investigate the long term effect of low exposure to radiation. The Committee noted that the consent of the cohort in the original study had not been sought due to different legislation concerning consent in the 1980s, and were mindful of the public interest in outcomes. The Committee also noted that some communication around this activity had taken place at the time of the original study, but there did not appear to be significant subsequent user involvement within the application.

Members queried why consent could not be obtained from the cohort once traced, and agreed that it was likely that the cohort would consent, and therefore efforts should be made to obtain this. It was not clear within the application whether it was practicable or not to seek consent, or whether the cohort were lost to follow-up, and therefore the Committee felt this should be explored further. It was discussed that due to the long term nature of the study and the relatively small numbers involved consent would be reasonably practicable and should be obtainable. The Committee also agreed that the cohort should be contacted to be informed that their identifiable data was being held by the research team.

Members were supportive of tracing the cohort via the Central Register as this was a reasonably practicable measure as the cohorts are already flagged, but were of the view that once traced then the GPs should be contacted and efforts made to seek consent for subsequent data. Should it be demonstrated that a large proportion of the cohort had been lost to follow-up or exited the NHS, then a further application could be made to the Committee to cover this proportion.

The study was provisional approved, subject to the following conditions of approval:

Conditions of approval

1. Section 251 approval had been provided to allow tracing of the cohort via MRIS. If traced, GPs should be contacted and consent sought by the GP or relevant healthcare professional. Should it be demonstrated that a significant number had been lost to follow-up / exited the NHS then a further application should be made to the Committee to cover this proportion.

2. Provision of a favourable REC opinion

3. That contact with the cohort must be via a GP or a health professional known to them

Action: NIGB Office to inform applicant of Committee decision

(e) Population based study of cytogenetic and clinical factors in leukaemia
[ECC 6-07(e)/2009]

This application sought access to the Northern & Yorkshire Cancer Registry and Information Service (NYCRIS) for linkage purposes, and access to hospital clinical records in order to examine the cytogenetic and clinical factors in a population based cohort of acute lymphoblastic leukaemia (ALL) and therapy related leukaemia (TRL).The purpose of this application was to determine the age specific incidence of these leukaemias, characterise the biology, determine the proportion of patients treated on a national clinical trial and investigate the type of treatment received by patients not entering a national clinical trial.

Dr Fiona Douglas made a declaration of interest in that she knew the site carrying out the research; however the researchers themselves were not known to her.

Members discussed this application in detail. They noted that the intention was to attempt to gain information via an extraction sheet provided to the clinical care team, however if that failed then the researcher would require access to hospital records. They were concerned that the possibility of consent had not been significantly explored. It was noted that around half of the cohort would be in the clinical trials run by a member of the research team at the time and it was queried why this could not be used as an opportunity to seek the consent of patients.

Members agreed that it was not clear why there was a need for ethnicity data, and were of the view that the section on user involvement could be significantly improved. The Committee were concerned that the question about user involvement had not been answered and this was a key factor which needed to be addressed before section 251 support could be granted.

Concerns were raised over germ line mutations and the Committee discussed that if the cytogenetic analyses might reveal germ line changes then this work should only be done on samples once anonymised or on samples for which consent has been obtained. If this was not the case then the researcher could potentially be put in a difficult ethical position where they cannot give the person the result as they might not wish to know and yet they would be holding important clinical information.

On the whole, the Committee agreed that it was not possible to approve the application in its current form and that a number of core questions would need to be addressed before reaching a final decision. The application was deferred pending clarification.

Request for clarification

1. It was not immediately clear within the application why consent was not possible, therefore the applicant was asked to provide further detail as to why they considered it was not.

2. The Committee considered that engaging with one person in terms of user/patient involvement was not sufficient and requested that this be revisited and more meaningful user engagement be conducted. The approach should be discussed with and tested with a representative group of patients if possible, and /or the possibility of linking with another clinician who could advise on suitable patient involvement.

3. If the cytogenetic analyses would reveal germ line changes then this work should only be done on samples once anonymised or on samples for which consent had been obtained.

Action: NIGB Office to inform applicant of Committee decision

(f) Evaluation of the linked antenatal and newborn NHS Sickle Cell and Thalassaemia Screening Programme: outcomes of newborn screening [ECC 6-06(f)/2009]

Kings College London applied for section 251 support in order to carry out a study to determine overall outcomes (mortality and entry into care) of all babies and children (up to 5) identified with sickle cell disease. Researchers required access to patient identifiable data from newborn screening laboratories and clinical networks for linkage purposes.

Members agreed that user involvement was excellent and that this should be commended. They also agreed that this was an important application and were sympathetic to its purposes. Members noted that due to small numbers full ascertainment would be beneficial. However one of the reasons given for not seeking consent was that there was a concern that some parents might not participate due to the potential stigma associated with the conditions. Members queried whether this amounted to dissent and whether section 251 support was being requested to effectively override dissent. Members referred back to the application, where they understood that the main reason for obtaining section 251 was to ascertain full coverage of the cohort. Members felt therefore that the reasons for not seeking consent from the cohort should be discussed in greater detail and this point explored.

The Committee commented that there did not appear to be an exit strategy defined in the application form and therefore queried how long section 251 would be required. It was also unclear how often the required information would need to be extracted. Further clarity over the overall purpose was felt to be necessary, as it was not clearly defined as to whether it was service evaluation, audit or research.

A point was raised that the database would hold information that might reveal something about paternity, as sickle cell anaemia and thalassaemia are both genetically recessive so a child would need to inherit a faulty gene from each parent. Therefore an expectant mother may refuse testing or deny having the disease if paternity was not as reported. The Committee felt that any resubmission should deal with this point.

The Committee remained mindful of the importance of the study and felt that the applicant should be given the opportunity to respond to the following issues before a final decision could be taken.

Request for clarification

1. Clarification of the aims of the overall screening programme and how well embedded this was.
2. Whether the application was seeking section 251 support to actively override dissent of mothers/parents.
3. Whether this was one-off ascertainment or a rolling programme of activity.
4. Members were unclear about diagnostic issues and the diagnoses being dealt with.
5. Clarification whether this was research or service evaluation or audit and justification over the respective case.
6. Confirmation of the exit strategy from section 251 support.

Action: NIGB Office to inform applicant of Committee decision

(g) Survival Analysis of a cohort of Clostridium difficile infected and non-infected patients admitted to Addenbrooke's Hospital between 2005-2007 [ECC 6-06 (g)/2009]

This application requested patient information to compare patients with C-difficile between 2005 and 2007 with a control group in order to determine survival rates. Support under section 251 was requested to permit access to MRIS data to undertake linkage and provision of mortality data, including death registration.

Members agreed that this is an important study and that the numbers involved were relatively small, however, they expressed concern over the level of justification provided within the application for not seeking consent. Members also indicated that the sample size may be too small to allow meaningful conclusions to be drawn. Members were concerned that no user involvement had been undertaken due to potential detriment to the reputation of the hospital, and did not consider this to be an appropriate justification. Members also noted that postcode was required but it was not clear why there was a need for this identifier.

Following clarification, it was agreed that the purposes of the application could fall under the specific support provided under the Health Service (Control of Patient Information) Regulations 2002, section 3 (1) of 'Communicable Disease and other risks to public health': sub section(b) recognising trends in such diseases and risks.

The Committee expected the HPA to strengthen their current plans for service user involvement and provide details of this within the annual review.

Action: NIGB Office to inform applicant of Committee decision

(h) Epidemiology and long term outcome of Pulmonary Arterial Hypertension (PAH) in the UK and Ireland 2000-2009 [ECC 6-06 (h)/2009]

This application from the Scottish Pulmonary Vascular Unit was for a study to investigate the characteristics of PAH in order to provide estimates of incidence and prevalence of PAH in the adult population in the UK. This information would then be used to identify predictors of outcomes and prognostics indicators. Section 251 was required for an external researcher to access, over a 12-month period, databases within PAH centres, hospital notes, clinic letters and medical records of patients to identify a cohort and extract information.

In considering this application, the Committee were concerned that consent had not appeared to have been explored in detail and were of the view that some of the relatively small cohort could be followed up because they were in contact with the service. Members were also concerned that, whilst Pulmonary Hypertension Association – UK (PHA – UK) had been informed, there appeared to be no evidence of substantive patient involvement, which the Committee would have expected to see within this study. Members noted that the application did not articulate how the principles of the Data Protection Act 1998 would be achieved.

Additionally, the remit of section 251 support extends to England and Wales but excludes Scotland and Northern Ireland, and as the applicant was based in Scotland, the approval would require a sponsor based in England or Wales.

On balance, the Committee was of the view that it would not be an appropriate use of section 251 to provide support to this application, and that consent would be a feasible option due to the relatively small numbers involved. Members also noted that where children were included in the cohort, consent should subsequently be sought from family members. The Committee did note that some of the cohort would be deceased and therefore if the applicant needed section 251 support to identify those who were deceased they could return to the Committee with another application.

The Committee advised that if the applicant was going to resubmit, a sponsor based in England or Wales would need to be identified and the application form would have to be completed in, full taking into account the Committee's earlier comments.

Action: NIGB Office to inform applicant of Committee decision

(i) The British Intestinal Failure Survey (BIFS) [ECC 6-06(i)/2009]

Leeds Teaching Hospital NHS Trust submitted an application for section 251 support which described a registry of children on longer term parenteral nutrition (PN) (defined as being on PN for 28 days or more) that was being developed to ascertain the incidence and outcome of intestinal failure, planning PN services, and predicting the need for paediatric transplant assessments. Section 251 support was requested in order to permit access to date of birth in order to obtain full coverage for the Registry and to prevent duplication.

Members noted that previous inclusion of information on the database was based upon informed consent and had been in operation for four years, and agreed that this was a worthwhile study and of public benefit. The Committee noted the reasons given in the application for not seeking consent for use of date of birth as an additional identifier was that consent was given by the parent/guardian (after the patient became eligible after 28 days of PN) and were often unavailable. The Committee were not persuaded by this view or the subsequent justifications given as it appeared there was a significant opportunity to seek consent due to the nature of the illness, and that most parents/guardians would have remained in close contact with their child and the clinical teams. Additionally, as the application indicated there had been limited dissent this added weight to the view that a consent approach would be entirely appropriate to pursue.

The Committee also noted that there had been no attempt to engage user groups and advised this should be explored as there were many relevant groups who could be approached.

Members additionally queried whether, instead of date of birth being required to remove duplications, month could be used instead, or whether NHS number would be suitable for the purpose. The Committee noted that this was likely to be available for this cohort as they had been admitted to hospital for a substantial length of time.

The Committee did not provide section 251 support to this application and stated that a consent approach would be reasonably practicable to pursue.

Action: NIGB Office to inform applicant of Committee decision

(j) Audit of the efficacy of screening colonoscopy in patients with a family history of Colorectal Cancer [ECC 6-06(j)/2009]

This application from Heatherwood and Wexham Park Hospitals NHS Trust described an audit of patients offered colonoscopy screening to ascertain effectiveness. Section 251 support was requested to allow access to patient data lost to follow-up via the National Cancer Registry and MRIS in order to determine whether there had been a diagnosis of colorectal/other cancer.

Members agreed that this was a reasonable study and that it was in the patients' interests and targeted those who would benefit most from the audit. Members noted that some areas of the

application form were lacking detail, for example the information relating to the Data Protection Act 1998 was sparse and the class support options had not been selected.

Members raised concerns about the assumption in section (s) of the application form that, by removing name, the data would be effectively anonymised. Members wished to note that there are other potential identifiers even if name was removed and identifiability depended upon the combination of data items. Members also highlighted a potential confusion arising in the application around the use of National Insurance number for tracing on MRIS and Members queried whether this should have been NHS number.

On balance the Committee decided to support this application and gave it provisional approval subject to the following conditions:

Conditions of approval

1. A copy of an up to date data protection registration with the Information Commissioners Office to be provided to the NIGB Office as the version provided had expired in 2008.

2. Full written responses to be provided on the sections on Data Protection in the application form to clarify how the study explicitly met each principle.

3. Confirmation whether the intention was to use NHS number rather than National Insurance number.

Action: NIGB Office to inform applicant of Committee decision

(k) Looking after ourselves: Integrated self-care in family practices [ECC 6-06(k)/2009]

The Institute of Health Services Research requested section 251 support in order for an external researcher to access GP patient lists, to assist practice staff with sampling, and to assist with mail outs of invitations to participate in the study.

Professor Sir Denis Pereira Gray declared an interest in this study and did not partake in discussions.

Members discussed this application in detail and balanced it against the Committee's core principle that initial approaches for consent should be made by a member of the cohort's clinical team or GP.

Members were sympathetic to the situation and noted that the applicant had provided details about the difficulty they had had in getting GP practice staff to carry out the activity. They also appreciated that the issue was not just based on lack on funding but also a lack of staff at GP practices. However, they did not consider the amount of time it would take the practice to carry out the administrative work was sufficiently significant to justify section 251 support. In particular, it was noted that it would not be appropriate to use section 251 to overcome administrative burdens.

In particular, Members noted that there would be researcher access to lists (and therefore patient identifiers) to aid the practice in sampling, and felt that this should be done by practice staff. Members also noted that the study picked GP practices at random and therefore could select another if one did not have the capacity to support them.

Based upon the balance of this activity, the Committee were unable to approve this application and recommended that the only reasonable method would be to either persuade staff at the current practices to carry out the mail-out, or to attempt to locate practices which could provide the administrative support required.

Action: NIGB Office to inform applicant of Committee decision

(l) An Evaluation of the Effectiveness of Different Treatment Pathways and Service Provisions for Adolescents with Eating Disorders [ECC 6-06(l)/2009]

This study aimed to explore and identify the different care pathways that exist for adolescents with eating disorders across Greater London and parts of Surrey and Hampshire, and to examine associations between these. Section 251 support was requested in order to permit an amendment to the study in which consent had been obtained, to add initials and date of birth to the tracking sheet of those who had not consented or had not responded to the invitation to participate, so that they were not sent repeat invitations.

The Committee noted that, whilst recorded by clinical teams, the information would be retained by those outside of the clinical care team. Members also considered to what extent and how far information should be retained on those who had actively dissented or failed to respond. This question arose, as a reason for the request for section 251 support was to avoid the problem of non-responders being sent repeat invitations; therefore this implied that the study was retaining information on non-responders. Members also considered whether non-responders should be classed as actively dissenting and in the application they appeared to be treated the same.

In considering this application, Members noted that the anonymised tracking sheet held on non-responders included information on age, sex and ethnicity and therefore adding initials and date of birth would render the form readily identifiable, and this in effect would be happening without consent and could therefore be classed as overriding dissent. A core principle of the Committee was that section 251 cannot be used to override dissent.

Members noted that the study also aimed to determine how many times people were attending the services and would therefore use the tracking sheets for this purpose. However it was still felt that to hold identifiable details would be overriding dissent and therefore section 251 could not be given for this purpose either.

Members were therefore unable to approve this application for the reasons given above and recommended that to avoid the problem of participants receiving repeat applications a paragraph be included in the letter that as more than one centre was involved in this study, the cohort might receive multiple invitations. Members advised that if those dissenting from the study did not want to receive further invitations they could be given the opportunity to contact the study and inform them that they do not require further requests when the initial consent form was provided.

Action: NIGB Office to inform applicant of Committee decision

(m) Ministry of Defence access to PDS via Demographic Batch Service (DBS) [ECC 6-06(m)/2009]

This application from the Ministry of Defence required section 251 to access NHS number from PDS in order to link with currently held identifiers to allow access to NHS Connecting for Health applications for service personnel and dependants.

Members were supportive of this application, and felt that, as the purpose of the data access was to support a patient's care and treatment, and it was not for a secondary purpose, that section 251 support was not required.

As such, the activity could proceed without the need for section 251 support.

Action: NIGB Office to inform applicant of Committee decision

(n) Access to NN4B data for validation of birth details [ECC 6-06(n)/2009]

This application from the West Midlands Perinatal Institute described a longitudinal data analysis of maternity and perinatal care to determine key factors which might influence perinatal mortality and morbidity in the West Midlands. Section 251 support was requested to permit data from the NHS Numbers for Babies (NN4B) service for births in the West Midlands to be sent to the Perinatal Institute to allow validation of maternity and birth data collected on behalf of West Midlands PCTs, Acute Trusts and SHAs. This would ensure completeness of coverage so that rates and occurrence of clinical events and conditions would be calculated against the correct denominator data.

The Committee noted that the Perinatal Institute had previously obtained section 251 support for a 12 month period whilst it developed its local processes for obtaining consent. This approval had expired and the applicant had informed the Committee that consent mechanisms were in place. In the process of considering the present application, the Committee considered the 'Consent Protocol'. It did not regard 'opt out' or the 'Opt Out Form' as conforming to current good practice in obtaining consent for the secondary use of data in this context.

Additionally Members noted that data was requested on all babies in the West Midlands and this would necessarily include babies whose mothers had opted out of allowing the use of their maternity records for secondary purposes. It was concerned that section 251 would be used to override dissent and could not agree to this. The Committee noted that where consent had been given, validation should not be an issue and section 251 would be unnecessary.

Members were of the view that the Perinatal Institute undertook very valuable work and that the validation process was important. However, it did not agree with the proposals set out in the application form and could not support the use of section 251 to override dissent. The Committee suggested that the consent protocol should be reviewed, to ensure current legal requirements are met and that, where consent was given, it was comprehensive and valid and covered all uses of the data.

Action: NIGB Office to inform applicant of Committee decision

(o) Cambridge Acute Stroke database [ECC 6-06(o)/2009]

This application from Cambridge University Hospitals NHS Foundation Trust set out the creation of a database to determine stroke outcomes where there has and has not been treatment. Section 251 support was requested for the use of local data obtained from two separate databases for observational study through creation of a new research database.

Section 251 was requested to cover the retrospective collection of data from the previous 5 years, and on a prospective basis.

Members discussed the application and subsequent clarification provided by email in response to NIGB Office queries. Members felt that the application lacked clarity in different areas. Members were not clear why an additional database was required as it would be extracting data from existing databases. They were also not clear whether the activity was research or audit and had difficulty identifying the research question that was to be answered. However, Members noted that it had been approved by a REC and had therefore been considered as research. The Committee were of the view that it could be considered as audit and queried whether it could be presented as such. If considered to be research then further explanation of the research purpose would need to be made. Members also queried whether the criteria for access to the database had been specified and recommended that this be the case so that it was apparent to patients. It was also noted that patient involvement was limited.

Members were concerned by the statement in the application that records might be identified by co-researchers provided that they had an honorary research contract. Members emphasised that honorary research contracts did not confer legal rights of access to patient records and therefore 'external' access outside the direct clinical care team such as this should not be provided on this basis. Members highlighted that access to patient identifiable information, outside of the clinical care team, and without consent, was a breach of confidentiality.

Members were concerned that the applicant had not considered the possibility of consent. Members noted that patients were asked for their consent to participate in other studies and therefore, consent for 'external' access (those outside of the direct clinical care teams who have not been involved in the care and treatment of the patient), should be via consent only. Additionally, the view was that consent, if necessarily specific, only applies to set studies and therefore that consent would not be transferable to the setting up of this database.

Action: NIGB Office to inform applicant of Committee decision

(p) Advancing Quality Programme [ECC 6-06(p)/2009]

NHS Northwest required section 251 to access health records from a variety of databases for linkage purposes, in order to provide information relating to the same patient but across various care settings and interactions. This would allow analysis to identify trends and to inform service improvements. Section 251 support was requested to access health records from a variety of sources including CDS, CCAD and MINAP so as to link data items from these sources.

Members agreed that this was an important study and were supportive of the purpose of tracking patient experiences. However, Members noted that it required a large amount of identifiers and the overall purpose was unclear. In particular, Members were concerned that consent had not been fully explored within the application and agreed that due to the large amounts of identifiers and linkages required that plans for consent should be actively pursued and these plans should be clearly articulated within the application. The Committee noted that the application stated large numbers as a reason not to gain consent, however the Committee questioned whether numbers would be as high as anticipated as the study targeted five particular conditions and therefore would not have to seek consent from all in-patients. It was also noted that subsequent correspondence had revealed a need for full coverage and the Committee queried whether the applicant was looking to override dissent. The Committee also

commented that there would be opportunity to consent as patients with the chosen conditions would be likely to remain in hospital for a few days in most cases.

Members advised that the application should be resubmitted to the February meeting, making clear areas where consent was not considered to be practicable, and where section 251 support might be needed as a temporary measure in moving towards a consent based approach. The use of identifiers would also need to be clarified and justified. Members also agreed that suitable user engagement should take explored and be reflected within the resubmitted application.

Action: NIGB Office to inform applicant of Committee decision

(q) Comparison of culture tools with holistic evaluation of an organisation's culture [ECC 6-06(q)/2009]

This application from City University London set out an assessment of quality of care in the labour ward and A&E department of eight hospitals via retrospective audits of patients' notes. Section 251 support was sought in order to permit access by an external researcher to medical notes in the course of carrying out the activity. The audit wanted to access 50 consecutive episodes of care.

The Committee considered this application in detail and noted that this study had already begun without section 251 support and the applicant had now been advised that this was necessary in order to proceed on a secure legal basis. Members considered the approach of writing to patients and acknowledged there would be the possibility of non-respondents, and noted that this approach might not achieve 50 consecutive cases. Therefore, Members debated the importance of 50 consecutive cases for the purposes of the study, and felt that this had not been fully justified within the application.

Members were sympathetic to the study and its current status and the approach previously taken in 2007 where it appeared that reasonable steps had been taken to attempt to obtain clerical assistance in carrying out the activity. However, Members agreed that these steps had been taken some time ago and therefore this difficulty should be overcome by seeking further attempts at a local level to obtain consent.

The data flows were discussed and concern was raised that it was not clear who would be handling what data; the Committee understood that whoever would extract data would not extract identifiable data but the application needed to be clear who would be carrying this out.

On balance, Members appreciated that there had previously been difficulties in seeking to obtain consent, however, they did not agree that issues over funding and lack of local resources was an appropriate justification for section 251 support and therefore a consent-based approach would be required. The Committee were unable to approve this application as it was felt that steps could reasonably be taken to seek consent to continue the activity.

Action: NIGB Office to inform applicant of Committee decision

7. Any other business

<u>Amendments to Regulations</u>

Members had suggested three revisions to regulations:

1. Medical research encompassed health service research but it was questionable whether it could also include social care services research. However Members agreed that if the research was commissioned specifically to support service evaluation then it may be reasonable to include such research under social care services management purposes under Class 5 support. It was agreed that Ms Karen Thomson would provide an update in progressing this issue at a later date.

2. Revision to allow linkage between data and tissue in line with the provisions of the Human Tissue Act and to allow identification of family members/nominated individuals for consent purposes in allowing access to deceased person's details if collected after 1 September 2006.

3. Revision of regulations to enable class 3 to be used to facilitate substituted decision-making via contact with the patient's 'representative'.

Children and Adolescent Psychiatry Surveillance System (CAPSS)

Members were informed that CAPSS was launched in April 2009 and they investigated national cases of rare childhood mental health conditions based upon the BPSU methodology. Members were informed that they had written seeking the Committee's views on whether CAPSS applications could be processed under section 251 in a manner similar to the BPSU methodology. The letter had been assessed outside of Committee and agreement reached in principle that this would be acceptable. The NIGB Office would contact CAPSS to set out the assurance activities that would need to be completed in order to progress this agreement.

8. Future meetings

1. 3 February 2010
2. 30 March 2010
3. 2 June 2010
4. 29 July 2010
5. 28 September 2010
6. 01 December 2010