Meeting held on Wednesday 25th March 2009

Present:

Members: Professor Dame Joan Higgins (Chair), Dr Patrick Coyle, Dr Tricia Cresswell, Ms Stephanie Ellis, Mr Michael Hake, Ms Ros Levenson, Ms Sue Parroy, Professor Sir Denis Pereira-Gray, Dr Mark Taylor and Mr Terence Wiseman.

External visitors: Professor Michel Coleman and Dr Bernard Rachet (item 6 ii),

In attendance: Mr Rick Borges *(NIGB Administrative Officer),* Ms Natasha Dunkley (*Approvals Manager*), Mr Paul Eveson *(Department of Health),* Ms Melanie Kingston (*Approvals Officer*) and Ms Zoë Lawrence *(NIGB Business Manager)*

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1. Welcome and Apologies for absence

1.1 Apologies for absence were received from Mrs Pauline Brown, Professor Mike Catchpole, Dr Fiona Douglas, Professor Roy McClelland and Ms Karen Thomson

1.2. The Chair welcomed Mr Rick Borges who attended as an observer

1.3 Professor Mike Catchpole declared an interest in agenda item ECC 2-06(a)/2009 as discussions over partial funding arrangements were taking place between the Health Protection Agency and Small Area Health Statistics Unit

2. Minutes of last meeting

2.1 The minutes of the previous meeting held on 27 January 2009 [ECC 1-02/2009] were agreed to be an accurate record and would be made available on the website.

3. Matters Arising / Action Points:

3.1 Secretariat report

<u>The Health Bill 2009</u>

Members were provided with an update on the progress of the Health Bill 2009, much of which was based upon the NHS Next Stage Review. As a whole, the Bill aimed to

improve the quality of NHS care and services, and to improve public health. Members noted that it placed a duty on providers and commissioners of NHS services to have regard to the NHS Constitution, which set out responsibilities of staff and patients.

It was reported that the Bill was at Committee stage and had been debated on 9 and 11 March, with key debates concerning the impact of the NHS Constitution.

ECC administrative review

The Secretariat reported that the review of ECC administration processes had been ongoing throughout February and March. The current processes had been mapped out, with a view to considering ways of streamlining, making improvements and introducing service standards where appropriate. Stakeholders had been consulted on their views and experiences in applying for section 251 support, and making HES and MRIS applications. The review was scheduled to conclude by the end of March. Following this an implementation plan of relevant recommendations would be developed and this would be presented at the next Committee meeting.

IRAS update

The Secretariat attended the regular IRAS Management Board and Project Board meetings on 10 March. Members were informed that an updated version of IRAS would be launched by 1 April to reflect a number of changes from the participating organisations. This would include the re-branding from the PIAG to the NIGB. Work was also in progress to ensure the HES form triggered properly as this had not been working for HES applications to the DMsG. It was reported that IRAS was the preferred route for research applications, and it was anticipated, where possible, to phase out the use of the former section 60 application form available on the website where IRAS could reasonably be used.

Members noted that in some IRAS applications not all questions had been completed. Members asked whether the facility to require applicants to complete all relevant fields could be investigated, as missing responses often focused around areas of primary concern to the Committee.

Action: Secretariat to investigate mandatory completion of relevant fields in IRAS

House of Lords: Surveillance: Citizens and the State

http://www.publications.parliament.uk/pa/ld200809/ldselect/ldconst/18/18.pdf

The House of Lords report, published on 6 February 2009, discussed the feasibility of consent in the fields of public health and medical research. It made reference to the Thomas-Walport Review and identified areas where there were practical difficulties in obtaining consent, for instance from children, the elderly, and incapacitated persons. The issue of consent also arose in relation to the collection and retention of volunteer samples on the National DNA Database.

It concluded that unless the obstacles and uncertainty were overcome, that the citizen would lack an important element of empowerment that could act as a safeguard. It welcomed the Information Commissioner's guidance on consent to data sharing, contained in his recent *Framework Code of Practice for Sharing Personal Information*. Members were informed that that House of Lords report made the following recommendation "we recommend that the Government, in conjunction with the Information Commissioner, undertake a review of the law governing citizens' consent to use of their personal data." It was not currently clear what this would entail and further information would be provided when it would become available.

Extensions under section 251

One extension was reported [PIAG 1-05(e)/2006 and MR1108]. This was an extension to link study data with the Cancer Registries HES extracts in order to check completeness and to obtain more timely notification of diagnoses. This extension was approved by Chair's action.

3.2 ECC Terms of Reference

The NIGB Business Manager provided an update on the status of the Terms of Reference and informed the Committee that their comments had been taken to the NIGB prior to final approval. Members noted that the Terms of Reference had been approved at the main Board meeting in February, with minor amendments around clarity over attendance, the role of Deputy Chair, and the requirement for the Committee to provide regular reports on its activities to the NIGB. The approved Terms of Reference would be published on the website.

3.3 Chair's report

Report from NIGB meeting

In line with the Terms of Reference, it had been agreed that the Committee would provide an update on its activities to the NIGB, and the ECC Chair would provide a reciprocal update to the Committee on the Board's activities via her Chair's report.

The Chair provided an update to the Committee on the second meeting of the new Board that took place on 18 February 2009. Professor Sir Denis Pereira Gray attended as an observer. The formal meeting was preceded by two working groups; the first discussed the piloting of patient access to electronic records in Hampshire, and the second heard presentations from GPES and the NHS Information Centre (NHS IC) on their information governance framework and proposals to establish a 'Compliance Unit' in the NHS IC. Colleagues from the Research Capability Programme were also present.

The Board discussed the information governance implications of the draft Coroners and Justice Bill and approved a draft letter from the Chair of the NIGB to the Secretary of State for Health. The Board had shared the ECC's concerns about clause 152 of the Bill, which proposed new wide ranging data sharing powers. It was reported that the clause has been withdrawn from the Bill and a letter would shortly be received from Ben Bradshaw, Health Minister that would confirm this position. It was expected that a new consultation would be issued on implementing more limited proposals.

The Board also discussed the information governance issues involved in social work conduct and practice, its communications strategy and a letter from Dr Paul Thornton on patient privacy and European standards.

Members raised the point that there were differences in social care around consent as these were typically more explicit than in healthcare. Members requested clarification on the situation where health information would be contained within a social care record. Members expressed the opinion that this would be likely to be an issue that fell within the common assessment framework and integrated working. However, Members agreed that it would be helpful to have a session on social care and its application to section 251; clarification over its boundaries and implications for the Committee.

Action: Secretariat to investigate the boundaries of social care information in relation to section 251.

The next meeting of the NIGB would take place on 15 April and the Chair asked Members to notify the NIGB Business Manager should they wish to attend as observers.

Appointment of NIGB members to the ECC

One of the requirements of the NIGB was that two of its members should be appointed to the Committee. The Chair reported that a number of applications had been received and that interviews would take place in early April, with the assistance of an Independent Assessor.

Caldicott conference

A conference for Caldicott Guardians had taken place on 25 February 2009. Over 500 people had attended and views were that the conference was very informative and lively. Plenary speakers included Dame Fiona Caldicott, Harry Cayton, Richard Thomas, Phil Walker and Christine Connolly. The Chair and Karen Thomson, NIGB IG Lead, held two workshops on the role of PIAG/ECC and section 251 powers. Both sessions were fully attended.

Meeting with the Information Centre

A meeting took place on March 4th with Tim Straughan, Chief Executive of the NHS IC, and senior colleagues to discuss ECC support for the development of their information governance strategy and the drafting of Regulations for Specific Support. It was envisaged that it would take approximately 12-18 month for specific Regulations to be completed, and that the Committee would advise the NHS IC where appropriate. Members noted that in the interim the NHS IC had been asked to supply a list of all activities where section 251 support was in place or required, as a first step in this process.

4. DMsG Report [ECC 2-04/2009]

It was agreed that all approvals of section 251 support authorised by the DMsG under delegated authority from the Committee would be formally reported at the Committee meeting. The DMsG Chair presented a written report (see Appendix 1) on the status of applications and approvals provided. It was also reported that since the application forms had been improved these applications were clearer to process and had become

more straightforward. A similar report would be provided for subsequent Committee meetings.

5. Applications previously considered

i. National Clinical Audit Support Programme [ECC 1-06(c)/2009)

This application was a resubmission from the NHS Information Centre (NHS IC) on behalf of the Healthcare Quality Improvement Partnership (HQIP). This application covered national audits in the areas of cancer, chronic heart disease, and diabetes in primary and secondary care. Support under section 251 was requested as responsibility for NCASP had transferred from the Healthcare Commission to HQIP on 1 April 2008. An annual review had not been submitted and approval had expired, therefore a further application from HQIP as the data controller had been required. This application was initially considered at the Committee's January meeting where a number of points had been raised and resubmission had been requested.

This application generated extensive discussion by the Committee, and Members were pleased to note that several changes had been made to the previous application that reflected the advice provided by the Committee in January. Members also accepted that there were difficulties in obtaining consent in relation to these audits, in certain situations. The Committee also welcomed the statement about the Care Record Guarantee (CRG) set out within the application and noted the NHS Information Centre (NHS IC) support to the principles enshrined within the CRG. The Committee were also pleased to note the information given about read-codes for dissent, specific to the context of diabetes. However, Members agreed that not all of the points of advice had been fully addressed in the resubmitted application.

On balance, as the Committee recognised that NCASP was an important and essential activity, and the application had met the minimum required standards, the Committee agreed that provisional, temporary, approval would be provided, subject to specific conditions, with a view to improvement of the application and NCASP practice. The Committee agreed to provide temporary support for a period of 4 months in the first instance, with the condition that support would only continue to be given on a rolling 4-month basis if demonstrable improvement and evidenced progress were to be provided at each review point at the Committee meetings in July and November 2009.

The Committee set out a number of areas for clarification and improvement:

- Members did not agree that there had been an appropriate response to its criticisms around the general difficulties in obtaining consent. Members accepted that there would be situations where consent could not be obtained from patients and this was likely to be the case when patients had suffered a heart attack. However, the Committee reiterated its view that the difficulties around gaining consent could not be generalised from this example. The Committee did not agree that the principles arising from this extreme example would necessarily apply in other situations, or that explicit consent would always be difficult to obtain.

- Members expressed concerned about the statement within the application that there were inadequate resources with which to seek consent or achieve pseudonymisation. The Committee noted that NCASP has an important role to play nationally and resources should be identified in the future. In its national leadership role it would be important for NCASP to set standards about consent and confidentiality. The Committee requested that more explicit plans should be developed to seek consent or to use anonymised or pseudonymised data in future applications.

- Members were not convinced by the statement within the application that those with long-term conditions would have consent sought repeatedly. Members noted that whilst these patients might have seen a series of clinicians in the course of their illness, there would be no reason why the seeking of consent would be burdensome if the patient were fully informed from the outset, and their consent was properly recorded.

- Members welcomed the comments made in section (p) about patient involvement within the audits. However, they were interested in the outcome of this involvement as much as the process of involvement. Members supported the principle that patients should be partners in their treatment and therefore requested specific evidence on how the patient input from MINAP and LUCADA had changed or influenced the approach within these audits

- The Committee noted the statement that "the disenfranchised and disengaged are less likely to be in a position to provide consent". The Committee considered these to be an important and potentially vulnerable group and requested to see further thought in the application about how this group would be reached

- Members noted in particular that the wording and messages, primarily in relation to section (o) 'Consent issues,' required clarification and re-wording, and advised substantially revisiting this section, taking into account Members' comments

- The Committee noted that certain parts of the application would need to be amended in line with its comments. The Committee would expect a formal initial review of progress to be submitted to its July 2009 meeting, in order to assess progress against the requirements set out in the provisional approval letter in order to determine the status of further approval.

The Committee emphasise that it understood and valued the importance of these audits, and that this was reflected through providing this interim approval under section 251 for an initial 4-month period, with subsequent approvals to be given on a similar rolling basis, where appropriate. The Committee noted that the NHS IC intended to progress activities around obtaining specific support that would potentially include the NCASP audits. Members noted that in the interim period it would be essential for the application and work of NCASP to reflect best practice.

It was agreed that a meeting would be set up with the NHS IC to discuss and clarify the implications of this approval decision.

Action: Secretariat to notify applicant of the Committee decision

ii. NCASP Hip Fracture UK [PIAG 4-05 (f)/2007

This application was withdrawn by the applicant prior to the Committee meeting and the Secretariat was notified that a revised application would be submitted in the near future.

6. New applications for section 251 support

i. Summary of Fast track applications [ECC1-06(FT)/2009]

Between the January 2009 and March 2009 meetings, the Committee considered two applications under the fast track process. It was noted that all applications were reviewed by both the Secretariat and the Chair in addition to the members listed under each application.

Extreme Hypernatraemia in newborn infants [ECC/BPSU 1-06(FT1)/2009]

This study into severely hypernatraemic infants aged less than 29 days old was from Bradford Teaching Hospitals. It followed the standard BPSU reporting card mechanism. This application was reviewed by Dr Tricia Cresswell and approved.

Count Me In 2009 [ECC 1-06(FT2)/2009]

This application from the Mental Health Act Commission Application was for the 'Count Me In' census of all in-patients, informal and detained, in registered mental health and learning disabilities services, taking place on 31 March 2009. A joint application had been requested from the Healthcare Commission and the Care Quality Commission (CQC) as the CQC would be responsible for the data from 1 April 2009 and it was likely that data would still be received after 31 March 2009. This application was reviewed by Professor Roy McClelland and Mark Taylor and approved.

ii. Discussion about consent in research

Professor Michel Coleman and Dr Bernard Rachet attended the meeting to present their views on issues about consent in relation to medical research.

iii. Small Area Health Statistics Unit (SAHSU) Health Database [ECC 2-06(b)/2009]

This application was from the Small Area Health Statistics Unit and support was requested under section 251 to hold datasets on births and stillbirths, cancer, mortality, NCAR and HES data for the purposes of advice provision, development of methodology to interpret health outcomes for small areas, and to act as a centre of expertise. This post coded health data would be held for a period for 5 years until April 2014.

The Committee considered the database to be of importance in this field of work and as, epidemiologically, large datasets would be required, the extremely large numbers would mean that consent would be impracticable. The Committee were supportive of this application as a whole and noted that it generally constituted good practice. The Committee agreed that at present, the purpose of the application was sufficiently defined

to fit within the classes of support, rather than specific support, however, a point was raised that a pseudonymisation service for postcode and other geomarker data would potentially be required in the future and that there could be the opportunity for SAHSU to investigate specific support as an 'honest broker'. Members also queried whether there was potential for overlap with the role of the NHS IC as they would hold similar datasets, and they were informed that this potential could be explored in the future.

The Committee therefore approved this application for a 5 year period from April 2009 – April 2014, subject to the following request for clarification.

The Committee noted that SAHSU would become part of the MRC Centre for Environment and Health from 01 April 2009 and that the contract would run for five years. Due to this change, the Committee requested clarification on the implications arising from this:

- Whether SAHSU or the MRC would continue to be the applicant.

- The Committee also requested assurance whether the same standards set out within the application would continue to apply post-April. If so, a written assurance would need to be provided to the Secretariat

- The Committee were mindful that the nature of the study would mean that it might be difficult to gain suitable input however, the Committee agreed that the response to section P should be strengthened to provide further information on how involvement via awareness-raising could be carried out.

When appropriate assurances had been provided, the Committee agreed that the application could be approved via Chair's action. Members also noted that this application highlighted the need for guidance to be produced on what the Committee would expect when there has been an organisational reconfiguration or change of name.

Action: Secretariat to notify applicant of the Committee decision
Secretariat to draft guidance on section 251 and organisational change

iv. Cardiovascular disease research using Linked Bespoke studies and Electronic Records (CALIBER) [ECC 2-06(b)/2009]

The purpose of this application from University College London was to create a database to better understand causes of coronary heart disease through identification of biological and environmental risk factors. Section 251 support was requested as the database required outcomes from yearly linkage of data from MINAP, GPRD and HES to establish the cardiovascular research platform.

Following discussion, the Committee noted that the application demonstrated significant efforts to utilise pseudonymisation and to follow good practice in this area. Members also agreed that this was a well constructed application that demonstrated very good user involvement.

The Committee agreed that section 251 support would not be required on the understanding that the applicants would not be in receipt of, nor hold, patient identifying information from GPRD or MINAP. However, Members agreed that it had been useful to review the application as there would be linkages with consented identifiable data, which

could result in the identification of individuals on linked GPRD or MINAP datasets, and that there would be onward disclosure to researchers.

Members commented that if the applicant agreed that the consented identifiable data would be maintained separately from the linked anonymised data, and third parties to whom data would be disclosed did not also receive any of the consented identifiable data, then section 251 support would not be required to carry out this activity.

Action: Secretariat to notify applicant of the Committee decision

v. Repeated implantation failure and impaired placentiation after IVF [ECC 2-06(c)/2009]

This application from Central Manchester and Manchester Children's University Hospitals NHS Trust and aimed to carry out a comparative evaluation of the incidence of pre-eclampsia between women who conceived on the first or multiple attempt with in-vitro fertilisation treatment. Support under section 251 was requested to carry out a case note review of 500 women between 2001 and 2007 and to carry out linkage between IVF and obstetric records.

Following confirmation from the Department of Health, the Committee were unable to consider this application at this meeting.

The study required access to data held by the Human Fertilisation & Embryology Authority, around which there are strict controls over disclosure. Some of these controls would change when the provisions related to the Human Fertilisation and Embryology Act 2008 and the disclosure of information would come into effect in October 2009. The information Regulations setting out the process for disclosure of information would come into force on the same date, and work was being carried out to investigate the role of the NIGB in this approvals process.

However, in this interim period, there were no transitional arrangements in place that would enact the exception in the new subsection 33A(2)(I) earlier than October. This meant that the current prohibitions on disclosure in the 1990 Act would apply and disclosure could not take place unless covered by section 33 within the current Act.

The Ethics & Confidentiality Committee did not have the remit to provide section 251 support to this application. It was advised that clarification be sought from the HFEA on whether the information requested could actually be used for research purposes. Alternatively, a consent based approach would be required, or if the information remained within the clinical care team and there would be no disclosure as to whether the cohort had undergone IVF then this could be a potential option to be explored.

Action: Secretariat to notify applicant of the Committee decision

vi. Risk adjustment in Neurocritical Care (RAIN) [ECC 2-06(d)/2009]

The Intensive Care National Audit and Research Centre (ICNARC) proposed an observational study to determine which physical locations of Neurocritical care are associated with improved outcomes for patients with traumatic brain injury. Support

under section 251 was requested to enable the collection of administrative, socio-demographic and clinical data in order to identify risk factors and medical details to follow-up with the cohort. Retrospective consent would be sought after six months.

The Committee agreed that the nature of the patient illness at initial contact stage would mean that many patients would initially be unable to provide consent, and that it would be important to capture detailed information at the time of admission. The Committee also noted that retrospective consent would be sought after a six-month period.

The Committee therefore approved this application on the basis that consent would not initially be feasible, but would be sought at a later date. This approval was subject to the following areas of clarification:

- Whether the data collected at time of admission (phase 2 of the study protocol) could be held locally until consent is obtained? It was noted that that this would mean deferral of data checking by 6 months.

- The application indicated that consent would be sought by the research team, however, one of the Committee's principles is that those directly responsible for the caring of the patient should make the appropriate contact where feasible. Members requested final detail as to why the consent could not be sought by the GP.

Once the above queries have been satisfactorily resolved, final approval given would be subject to the following conditions of approval:

- Satisfactory REC approval (letter to be provided)

- Section 251 support applies solely to England and Wales, therefore Scotland and Northern Ireland would be excluded from the scope of approval

- In cases of incapacity to give consent, this decision should be taken by next of kin and not by the appropriate consultant, in line with the Mental Capacity Code of Practice

- Members noted there had been some attempts to involve patient groups, however, further involvement from the appropriate patient groups would be required

Action: **Secretariat to notify applicant of the Committee decision**

vii. Prospective analysis of bruising in children [ECC 2-06(e)/2009]

The purpose of this application from Cardiff &Vale NHS Trust was to prospectively assess incidences of bruising patterns of children suspected of experiencing physical abuse, but where this abuse has not been substantiated, in order to aid diagnostic accuracy. Section 251 support had been requested in order to enable the researcher to access clinical records of children, for comparison against a control group where abuse had been confirmed.

Following detailed discussion, the Committee were unable to approve this application in its current form as a strong justification had not been provided to enable support under section 251.

Members noted that the study appeared to be both prospective and retrospective, and it was not clearly set out what section 251 support had been requested to cover. Members also agreed that a suitably strong case had not been made to explain why consent could not be sought and it was recommended that this issue should be significantly reassessed. The Committee also noted that a response to question 15-2 had not been provided. The Committee requested the applicant to provide a strong justification to explain why consent could not be sought from this cohort. Members requested that, should the applicant have demonstrable evidence that consent would not be feasible, then the Committee would accept a future application for section 251 support to cover a retrospective study of the 500 patients. Members suggested considering the feasibility of the situation where the data would be extracted by a clinician who could then forward the data in an anonymised format to the researcher.

Action: **Secretariat to notify applicant of the Committee decision**

viii. Paediatric Palliative Care in Yorkshire [ECC 2-06(f)/2009]

This application from the University of Leeds intended to develop a research database that would hold clinical and demographic data on children suffering from life-limiting and life-threatening illness in order to assess current services and inform future service planning. Section 251 support was requested in order to enable access to clinical and demographic data on the cohort to maintain the database.

The Committee had a detailed discussion regarding this application and noted that it was not clear whether the data was currently in use or whether it would be used. The Committee noted that a database referred to in the application appeared to have been in operation for the previous 21 years, however, Members agreed that section 251 support could not be given to legitimise a previously existing database without sufficient evidenced justification. Members noted that if the data held in the database derived from NHS-commissioned care than it would be within the Committee's remit to comment, however, if not then the Committee would not have the remit to decide on this aspect.

Members noted that the application appeared to border on research, audit and service planning, and were concerned that the data to be used was for a non-NHS hospice. It also appeared that the study was actually a health-needs assessment, although this was not what had been described.

Members were of the view that as there was no research hypothesis the purpose of the application centred on service planning rather than research, and therefore S251 support could not be provided. Members agreed that if the applicant considered the purpose of the study to be research, then the Committee would consider a resubmission, setting out the research proposal, and detailed evidence why consent could not be obtained, along with details as to further user involvement, at a subsequent Committee meeting.

Members were also of the view that the small numbers involved, the level of patient contact, and the beneficial nature of the database, as stated in the application, would

mean that the cohort population should be willing to cooperate and therefore consent should be sought. Any resubmission should therefore fully explore this point.

Action: **Secretariat to notify applicant of the Committee decision**

ix. Surveillance of Paediatric Bipolar I Disorder in the UK and ROI [ECC 2-06(g)/2009]

This application from the University of Newcastle was to carry out a surveillance study to investigate the prevalence, diagnostic features and short term outcomes of PBID in children under 18 years old in order to inform future service provision. Support under section 251 was requested as the study required access to clinical and demographic data over a 12 month period to identify the number of new cases, co-existing mental health conditions, treatments and reoccurrences.

Members agreed that this was an important piece of research, and highlighted that the patient involvement as set out in question 15-1 was particularly well-carried out.

The Committee were unable to approve this application at its meeting, however, Members agreed that, if possible, the application should be resubmitted for the May meeting taking fully into account the following points:

- To give consideration as to whether identifiable patient data would be required and whether it would be possible to report solely against the NHS number and use this as a basis for follow-up. Members requested that a pilot study be carried out to test the feasibility of solely using the NHS number (see point 2 below) and testing whether seeking consent would be possible. This would then provide evidence which can be included in a resubmitted application as necessary.

- Members considered the cohort size of 900 to be a relatively modest number and queried why consent could not be sought as, although it would probably be reasonable for consent not to be obtained on the first visit, the cohort are followed up and it would be possible for consent to be sought at a subsequent date

- As the cohort consisted of children, typically, parental consent would be required and Members requested for this point to be addressed within the pilot study.

- Members also requested further detail on the reason why the cohort's GP would not be informed of the study and requested confirmation over the position as to whether it would it be possible to reduce the date of birth identifier to age

Action: Secretariat to notify applicant of the Committee decision

x. 2009 Attribution Data Set (ADS) [ECC 2-06(h)/2009]

This application from the Department of Health requested support under section 251 to access the full postcode of all patients registered with a GP in England and Wales in order to establish a dataset for the purposes of NHS Resource Allocation.

The Database Monitoring Sub-Group (DMsG) had referred this application to the Ethics and Confidentiality Committee because the full postcode, which is a potential identifier, had been requested.

Members agreed that use of full postcode meant that the data was identifiable, and that it would not be practicable to seek consent for use of postcode from the general population. The Committee discussed this application at length and recognised that this was a business critical activity and it was noted that the activity was scheduled to take place imminently. Members raised the general point that where critical activities required s251 support, applicants should ensure they approach the Committee as early as possible in order to ensure a legitimate basis for access to identifiable information.

The Committee noted that the security arrangements set out in the application raised a number of concerns around appropriate information handling. Due to the seriousness of these concerns, the Committee decided to defer this application to the May meeting pending an assessment by the security advisor concerning the arrangements as set out in the application.

Members also requested that consideration should be given to strengthening the section in the application on patient involvement and providing further detail on this aspect. The Committee noted that there had been limited patient involvement and plans to address this issue should be included, such as involvement of Local Involvement Networks.

Action: Secretariat to notify applicant of the Committee decision

xi. GP Market Share Analysis [ECC 2-06(i)/2009]

This application from the Department of Health proposed to assess the level of competition existing between general practices. Section 251 support was requested as the study required access to the Attribution Data Set and postcode data to identify the patient's distance from their practice, in order to determine aggregated indicators of market share for each practice.

The Committee were supportive of this application and noted that the study required access to identifiers for a short period of time, however, as the data source was the same as the ADS application and had the same security arrangements in place, the Committee also decided to defer this application to the May meeting, pending an assessment from the security advisor on the contractor security arrangements as set out in the application.

Action: Secretariat to notify applicant of the Committee decision

xii. Investigation into the relationship between OASys and PCL-R scores [ECC 2-06(j)/2009]

This application from HM Prison Service aimed to investigate the relationship between Psychopathy Checklist Revised (PCL-R) and the Offender Assessment System (OASys) assessments in order to test the efficacy of OASys as a risk management screening tool. Support under section 251 was requested as the study required access to identifiable assessment data that was to be used for a purpose different from the original purpose for which it was collected.

Following extensive discussion, the Committee were of the view that the purpose of the study did not appear to be a medical purpose as defined within the Health Service (Control of Patient Information) Regulations 2002. Members were of the view that as the tools used were for assessment and offending and dealt with offender management rather than healthcare, that this would fall outwith section 251.

It was decided that, should the applicant demonstrate that this study fit within an appropriate medical purpose, then the Committee would reconsider the application through re-submission to its May meeting. Members requested that the resubmission would need to provide evidence as to why consent cannot be sought.

Action: Secretariat to notify applicant of the Committee decision

xiii. Factors associated with length of stay in a medium secure unit [ECC 2-06(k)/2009]

This study from East London NHS Foundation Trust aimed to identify characteristics as predictors of prolonged stay of service users in a medium secure psychiatry unit. Section 251 support was requested in order to carry out a retrospective pilot study and access the cohort's clinical notes.

The Committee agreed that this was an important study and were supportive of the purpose of this application as it was seeking to improve treatment. Members also noted that there would be difficulty in tracking patients in prison due to security issues. The Committee therefore approved this application, subject to the following conditions:

- Members were of the view that whilst in some instances consent would not be feasible, there would be situations where consent could be possible. Those still in contact with the service should be approached for consent by members of the clinical team responsible for their care, and dissent be respected.

- Members noted that there was no evidence of user involvement and considered that that it was feasible to develop this, therefore suitable user involvement should be carried out at an early stage.

Action: Secretariat to notify applicant of the Committee decision

xiv. Stroke Survivor Needs Survey [ECC 2-06(l)/2009]

This national comparative survey from Kings College London aimed to identify the frequency of unmet needs of stroke survivors between 2004–2008. Section 251 support was requested as the study would involve the disclosure of the cohort's contact details from the Medical Research Council General Practice Research Framework (GPRF) to research nurses for consent purposes.

Members noted that the purpose of the study was an important one and that access to the cohort's contact details was to enable the applicant to seek consent. However, Members expressed concern over the use of research nurses outside of the clinical care team obtaining access to identifiable patient information. Members agreed that, should clinicians carry out the recruitment, this would entail approximately 6-8 patients being recruited per practice, which should be a manageable number. The Committee agreed to provide support to this application, subject to the following conditions:

- As the study involved small numbers and involved a common condition, the initial identification should be carried out by members of the cohort's direct clinical care team

- This support extends only to England and Wales; Scotland and Ireland fall outwith the remit of this support.

Action: Secretariat to notify applicant of the Committee decision

xv. Improving Stroke Recognition by Ambulance Services (ISRAS) [ECC 2-06(m)/2009]

This study from the London Ambulance Service NHS Trust proposed to carry out a comparison of patient assessment tools and their efficacy when used by ambulance staff in recognising stroke symptoms. This application required support under section 251 as it required prospective access, by a staff member outside of the clinical care team, to stroke assessment tool data and patient contact details in order to track progress.

The Committee strongly supported the purpose of this study and noted that the application had set out significant measures to ensure that the process was as fair as possible and had anticipated and mitigated a number of consent issues; however, Members were concerned that the initial recruitment would be carried out by persons outside of the cohort's clinical care team. It was the Committee's view that such contact should be made by a member of the direct clinical care team unless it could be demonstrated that this would be impracticable.

On balance, the Committee decided to provide support to this application subject to the following condition:

- Where feasible, retrospective consent should be sought by a member of the clinical care team on behalf of the researcher

Action: Secretariat to notify applicant of the Committee decision

xvi. National Cardiac Arrest Audit [ECC 2-06(n)/2009]

This study from the Intensive Care National Audit and Research Centre (ICNARC) sought to identify improvements in the prevention of in-hospital cardiac arrest and outcome data within NHS acute hospitals through a feedback process. Support under section 251 was requested as the study required access to data to monitor and report on incidences and outcomes from in-hospital cardiac arrest. Members noted that this study was linked to an existing approval [PIAG 2-10(f)/2005].

The Committee considered that the purpose of this application covered a clearly important issue, and that the reasons given for not seeking consent at the outset were reasonable.

However, due to a number of areas requiring clarification, the Committee decided to defer this application so that the following points could be addressed. It was agreed that should the points be satisfactorily addressed, a final decision could be taken by Chair's action.

- Members requested a full explanation as to why retrospective consent could not be sought as the Committee were not convinced that selection bias was an appropriate reason to justify support in this instance. It appeared to Members that consent could be sought and the wider issues around consent should be addressed.

- It appeared that identifiers would be retained indefinitely and then would be linked with other datasets. Members requested further information on what this would entail

- It was not clear to Members why ethnicity would be required, therefore an explanation for the use of this identifier was requested

- The Committee were concerned over the statement about mental capacity and requested that this statement be revisited, taking into account the earlier point made around consent.

Action: Secretariat to notify applicant of the Committee decision

xvii. The Study of Suicide in the Criminal Justice System [ECC 2-06(o)/2009]

This study from the National Confidential Inquiry into Suicide and Homicide at the University of Manchester aimed to investigate suicide across the criminal justice system to investigate whether those involved with the CJS were at heightened risk of committing suicide.

The Committee were sympathetic to the purpose of this application. It was noted, however, that control groups could be vulnerable in terms of access and consent. The Committee was unable to take a decision at this meeting and deferred this application.

Members requested that further information and evidence be provided to explain why consent can or cannot be sought from the control group. It was agreed that should a satisfactory response be received a final decision could be taken via Chair's action.

Members also noted that it would be helpful to have the issue of control groups placed as an agenda item on a future Committee away day.

Action: Secretariat to notify applicant of the Committee decision
Control groups to be placed as item for discussion on away day

xviii. Emergency Stroke Calls: Obtaining Rapid Telephone Triage – Phase 8 [ECC 2-06(p)/2009]

This application from the University of Central Lancashire aimed to evaluate the impact of training packages and protocols on the accuracy and timeliness of stroke diagnosis using time series analysis to inform an Emergency Call Package. Section 251 support was required in order to allow prospective access to ambulance data in order to link to the stroke register so as to confirm the accuracy and timeliness of the initial diagnosis.

Following consideration of this application, Members were of the view that this study consisted of a service evaluation rather than research, as the purpose was to advise emergency medical crews. Additionally, it was noted within the application that REC approval had not been required and any support under section 251 requires REC approval. The Committee also noted that identifiers would be held for a short period of time.

As such, it was considered that as this study consisted of a service evaluation section 251 support would not be required in order to carry out this evaluation.

Action: Secretariat to notify applicant of the Committee decision

7. Any Other Business

7.1 Applications

The possibility was raised of the Members being provided with copies of all applications. Currently, each application is allocated to four or five members, who are identified according to their areas of expertise. Re-submission, particularly contentious, wide-ranging, or applications raising issues of significance would be sent to all Members. All members would receive a summary of all applications that provided an outline of the application including key issues around consent and patient involvement. These reviewers would then lead the discussion on the application within the Committee. The variation to this current procedure was discussed at length by the Committee and it was agreed that in order to ensure all applications were reviewed with a sufficient amount of

rigour, and to ensure that all applications had the necessary amount of scrutiny devoted to them, the current process would continue. Members were notified that spare copies of all applications would be tabled at the meeting and should a Member want to discuss an application then they could request a copy from the Secretariat.

7.2 ECC Deputy Chair

In line with the terms of reference, Members were notified that nominations would shortly be sought for the role of ECC Deputy Chair. This action would be followed up by the NIGB Business Manager and Members would shortly be contacted regarding nominations.

7.3 Complaints and Appeals policy

The NIGB Business Manager presented the draft Complaints and Appeals policy. Written comments were provided by Professor Sir Denis Pereira-Gray and Members were informed that the policy was scheduled for approval at the main Board meeting in April.

7.3 Date of further meetings

May 21st
July 20th
September 21st
November 24th