Meeting held on Tuesday 2 February 2010

Present

Members: Dr Andrew Harris (*Chair),* Mrs Pauline Brown, Dr Tony Calland, Professor Mike Catchpole, Dr Patrick Coyle, Dr Tricia Cresswell, Professor Carol Dezateux (*arrived at agenda point ECC1-04(a))*, Ms Stephanie Ellis, 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),* 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

The Chair welcomed Members and thanked them for their support in his new role.

Apologies were received from Dr Fiona Douglas, Professor Sir Denis Pereira Gray, Ms Ros Levenson and Professor Roy McClelland

2. Minutes of last meeting [ECC 6-02/2009]

Minutes of the last meeting held on 24 November 2009 were approved, subject to minor amendments.

NIGB Office Report [ECC 1-02(a)/2009]

ECC Appeals

Members were informed that the NIGB had used the Appeals and Complaints process on two occasions following decision outcomes of the Committee. In light of the practical experience of the procedure in use it had been reviewed and the updated version had been re-issued on the NIGB website. Members were advised that the revised version allowed more flexibility in timing for the appeal procedure but remained within the 20 day overall time limit.

National Research Ethics Service (NRES)

Members were informed that a meeting had taken place between the NIGB Office, Fiona Douglas and NRES colleagues in November. The meeting had taken place to discuss the interface between the application process for Research Ethics Committees (RECs) and the ECC. A draft memorandum of understanding (MOU) was to be prepared to set out how these interfaces would be managed and to improve the application processes. Members were advised that a further meeting was to be held and the MOU would hopefully be ready to be shared at a future ECC meeting.

Research Database Working Group

At the NIGB Board meeting in October 2009, the ECC had reported an increase in the number of applications it had received from clinicians and academic departments to establish research databases using patient identifiable information. In addition to this it was also reported that there had been an increase in the number of requests to local research committees to give "secondary permission" to researchers to access data held in such databases, The ECC had proposed that the NIGB should establish a working group to assess the nature and scope of this problem and make recommendations on practice. Members were informed that the small working group had been established and included membership from the NIGB, the ECC and two external experts. External representatives were also part of the working group, e.g. representatives from National Research Ethics Service (NRES) and National Cancer Intelligence Network (NCIN).Mark Taylor, ECC member, would chair the group which would meet for the first time in January. It would report to the NIGB during the summer. Draft terms of reference were provided to Members for comment.

Mark Taylor provided a short update to the group and discussed amendments to the proposed draft terms of reference. The definition of confidential patient information within the terms of reference was amended to that given within section 251 of the NHS Act 2006. An additional term was also added in order include a broader definition of confidential patient information in relation to when information custodians could disclose information for secondary purposes.

Members agreed to provisionally agree the terms of reference subject to the proposed changes being made and ratification by the NIGB.

Action: Research Database Working Group terms of reference to be amended.
Action: Research Database Working Group terms of reference to be ratified by the NIGB at its meeting on 24 February.

Summary of Responses to the Consultation on the Additional Uses of Patient Data

Members had previously been provided with a copy of the outcome to the Department of Health consultation on secondary uses of patient data. Members were informed of the key points that related to PIAG and the approval process that arose during the regional stakeholder groups.

Members discussed the Report and noted that the NIGB might wish to discuss the perceptions arising from the Report.

ECC annual review visits

Members were advised that the NIGB Office had begun conducting site visits alongside the standard annual review process for selected applications. The purpose of the visit was to discuss submitted annual reviews in more detail for some of the more complex studies with section 251 support.

The visits would involve a discussion of the study and review progress against any specific conditions of approval, as well as a view of the information governance arrangements. The aim of the visits was to support applicants during their study and to pre-empt any difficulties in meeting conditions of approval.

UK Biobank had received support under section 251 in order to carry out the cohort invitation process, and a report of this visit was provided to Members for their comments. [PIAG 4-06 (b)/2006] The report recommended continued section 251 support.

Members noted that the recruitment phase had not yet been completed and that the target date for completion was June 2010. Members were also pleased to note that the requested changes to the GP leaflet had been made. Members discussed the report provided to them on enquiries and complaints and noted that UK Biobank had their own Ethics and Governing Council which considered issues raised by these complaints along with other ethical issues. Members were satisfied that the activity was continuing as planned and therefore approved this annual review.

Action: NIGB Office to inform UK Biobank of Committee decision.

Fast Track applications

1. Evaluation of antenatal syphilis screening, management and infant outcomes ECC 6-07(FT1)/2009

   This application from the UCL Institute of Child Health was considered by the smaller number of Members and approved in November but after the November papers had been distributed.

   This study indicated that there was currently no comprehensive systematic national surveillance system for infectious syphilis in pregnancy or cases of congenital syphilis, and that there would be linkage with a related BPSU study of congenital syphilis. The study aimed to evaluate the national antenatal syphilis screening programme, monitor the management and outcome of pregnancies in which infectious syphilis is confirmed, and provide evidence for improving current screening and management strategies.

   Members considered that the issue covered was an important one, and that the methodology was robust and had been well tested. It was agreed that the amount of requested data was reasonable and the identifiers requested had been justified. It was noted that this covered a sensitive topic and that significant efforts had been made to preserve anonymity of participants and that the initial extraction of data would be carried out by the clinical team.

   This study was approved by Deputy Chair's action, pending satisfactory security arrangements.

2. Surveillance of Gonorrhoea, Syphilis, Chlamydia and Trichomonas infections in children aged under thirteen years presenting to secondary care [ECC 1-03 (FT1)/2009]

   This application from Norfolk and Norwich University Hospital was considered by a smaller number of Members outside of the usual Committee schedule as the study followed the British Paediatric Surveillance Unit (BPSU) approved methodology. This was a surveillance study to allow the epidemiology of sexually transmitted infections in children to be investigated. The information collected from the study would help inform the paediatric advice to child protection services.

   Members considered that the application was clearly set out, followed robust BPSU methodology and that the issue covered was an important one. It was agreed that consent would not be practicable and that the identifiers requested had been justified. It was noted

that this covered a sensitive topic and that the REC approval had set out important conditions to be met before the study went ahead.

This study was approved by Chair's action.

3. MR1175 Prospective study of Outcomes in Sporadic versus Hereditary breast cancer (POSH)

This was an application from the University of Southampton to allow the flagging of the study cohort on the MRIS database for deaths, cancer, PCTs and exits. This had been considered outside of Committee as the issue was around the validity of consent taken and it had been agreed that these could be fast tracked under certain circumstances. It was noted by the smaller number of Members outside of the usual Committee schedule that the original consent obtained in the study had been for long term follow up and did not specifically mention flagging within MRIS. Members considered that the study was in the public interest and noted that it had favourable service user opinion. It was agreed that section 251 approval should be granted as the cohort had consented to follow up of their health status and that the aims of the study were clearly within the spirit of the original consent.

This study was approved by Chair's action.

4. PIAG 4-05 (d)/2007 Time extension of Central Register

Following discussions with the NIGB Office and Chair, it was agreed that due to timing issues, this application from the NHS Information Centre would be extended to 10 February 2010. This was to allow sufficient time for a fully revised application to be submitted to the Committee at its February meeting.

This time extension was approved by Chair's action.

5. Annual Review BANS

Following approval of pseudonymisation as an appropriate exit strategy, it was noted that this study no longer required support under section 251 to proceed.

Update on previous November applications

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

Members noted that the SUS application had been fully approved following the satisfactory clarification of outstanding issues. Members were informed that the Committee did not approve the aspect that related to the flow of Patient Pathway Identifier (PPI), Organisation Code of PPI Issuer and post-code from GUM service providers to SUS. Members had also queried whether partial postcode would suffice. The response to this had been that partial postcode would not be fit for purpose and the intention would be to submit a further paper to the Committee for further consideration on this aspect.

[PIAG 2-05(d)/2009] Dr Foster Annual Review

The applicant had clarified that there would be no other linkages with other data sources and that identifiers were stripped put on a rolling annual basis once the data was three years old. The annual review had been subsequently approved.

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

This application had been provisionally approved at the November meeting subject to clarification as to how the applicant would deal with non-responders. Following further clarification of the issue, the application was approved by way of Chair's action.

[ECC 6-06(e)/2009] Population based study of cytogenetic and clinical factors in leukaemia

This application had not been approved at the November meeting as Members felt that the applicant had not explored in enough depth why consent was not feasible and had not justified why ethnicity was required. In addition, there was limited patient engagement. Following further discussions with the applicant, it had been agreed that they would engage with a contact at Leukaemia Care, whose role was to facilitate user involvement in research studies, with a view to establish a user group.

ECC Chair's Report

National Information Governance Board

A meeting of the NIGB was held on 16 December 2009 and the Chair provided an update on the issues discussed.

Personal Demographics Service

Representatives from the Demographics and Spine Directory Services and National Demographic User Group provided a presentation and sought advice from the Board on their document, 'Information Governance Requirements for the Personal Demographics Service (PDS)'. It was confirmed that the NIGB endorsed the Care Record Development Board's position on the use of personal demographic information (which stated that this information should be treated as confidential and used for its primary purpose to support the provision of care). Concern was expressed about the level of security required to access PDS which was username and password (eGIF 2). Members were reassured that staff with eGIF 2 level access could not access a patient's clinical data, only demographic information, unless the same member of staff had an appropriate role to access clinical information.

Honest Brokers

The NHS Information Centre (NHS IC) provided a presentation on the role of the Honest Broker. NIGB Members recognised the potential benefit of honest broker services in reducing the flow of identifiable data whilst also increasing the quality and utility of data. The NIGB agreed that whilst the criteria and attributes set out in the paper were helpful, they needed further development. The NIGB would have the opportunity to consider the standards that would apply to the NHS IC's honest broker services in February 2010 when the Information Governance Framework would be presented.

ContactPoint

Representatives from the Department for Children, Schools and Families presented to the Board on the implementation of ContactPoint, an online directory with a record of every child in England, accessible to authorised practitioners especially to safeguard vulnerable children.

Role Based Access Control (RBAC), NHS Connecting for Health

Representatives from NHS Connecting for Health (NHS CfH), provided a presentation to the Board on the Registration for the NHS Care Record Service. Role Based Access Control (RBAC) was developed so that access to patient data was limited according to the particular role being undertaken by a staff member and the workgroups to which they belonged. NHS CFH would be replacing RBAC with Position Based Access Control (PBAC) which provided access to patient information based on job instead of to a named individual. Advice was sought from the Board on the integrity of audit trails when health professionals sharing a single smartcard in some circumstances such as in Accident and Emergency (A&E) units where there was a need for a rapid changeover of computer use between staff members. Members felt that sharing smartcards was not good practice and that the principles in the NHS Care Record Guarantee should not be changed as it was important for medico-legal purposes of knowing who was responsible for particular clinical decisions or for administering treatment.

Policy update from the Chief Information Office, Department of Health

The DH had published the 'Summary of Responses to the Consultation on the Additional Uses of Patient Data'. It would establish pilots to explore means of patients opting out of having their medical records used for research purposes. The Ministry of Justice had published a response to the Database State Report published by the Joseph Rowntree Reform Trust. The Board was also informed that the current government had no plans at present to take forward measures to bring data sharing provisions into legislation.

3. Resubmitted applications for section 251 support

a)Evaluation of linked antenatal and newborn Sickle Cell and Thalassaemia Screening Programme [ECC 6-06(f)/2009]

This application from King's College London set out the assessment of newborns' overall outcome and timely early entry into care of all babies identified with sickle cell disease. Information would be retained until the child was 5 years of age to allow follow up. Section 251 support was requested in order to collate patient identifiable data from newborn screening laboratories and clinical networks programme for linkage purposes.

This application was considered at the November ECC meeting where Members felt unable to provide section 251 support and requested further clarification of key issues, such as uncertainty over the aims of the programme, whether the programme was research or audit and a lack of exit strategy. These clarifications had subsequently been provided and assessed by the Members who considered the original application. The Members concluded that the application should be bought back to full Committee due to concerns that section 251 support was being sought to override dissent and that the application lacked an exit strategy.

The Committee considered this to be a highly important programme and were sympathetic to the sensitive cultural issues inherent in the diagnosis of sickle cell and thalassaemia in babies. Members noted that the programme wanted to identify those children whose parents had refused screening but later developed sickle cell disease and that this was a very small number. Members discussed at length whether this could be amounted to overriding dissent.

After detailed consideration, it was agreed that it was not known if parents were dissenting from the screening programme or passively not taking advantage of the screening programme for their children. Assumptions could not be made about whether dissent had occurred and whether or not this would include or not the use of information about cases for evaluation of

the screening programme. Members were mindful that section 251 could not be used to override dissent when using medical information for a secondary purpose. Members also discussed that the screening programme offered significant benefits to children at risk of the condition and felt that on balance the benefits of the programme outweighed the theoretical risk of overriding dissent for information processing in a small number of cases,. Members also noted that some of the cohort would be lost to follow up and therefore it would be extremely difficult to find and obtain consent for information processing from them.

In order to ensure that the rights of individuals and patient benefit were balanced, Members agreed that when in contact with the screening process the cohort must be provided with clear information about the programme and how the data would be used. This should include the right of the patient to opt-out from the programme and if individuals were to opt-out, then all identifiers must be stripped out.

Members agreed that the ideal situation was for NHS Number to be used as the identifier for linkage purposes, however, it was noted that often the children could have been in contact with a number of healthcare settings and different NHS systems. This would make linkage via a common identifier difficult due to these disparities. Additionally, Members noted some inconsistencies over recording of name in some ethnic minorities which also added to the problem of using a constant identifier.

Members noted that the Data Protection compliance section of the application required further clarity and noted that any approval should be subject to satisfactory completion of this section.

On balance, based on the inconsistent use of NHS Number within the NHS, the fact that dissent was not being overridden and the high public benefit in the outcomes of the programme, Members agreed to provide section 251 support to the application. Members noted that approval would be provided for one year, by which time they would expect to see progress on how the Programme would help to influence consistent use of NHS Number within all newborn babies. The approval was subject to the following conditions:

1. That a patient information leaflet including a right of opt-out be provided to all those attending screening and be publicised. The right to opt-out should be made explicit within the screening programme. An example of the leaflet was to be provided to the NIGB Office.
2. That where possible the use of NHS Number was to be incorporated as part of an exit strategy.
3. That the approval was provided for one year and at annual review a report should be given with details how the applicant was working with relevant organisations in the promotion of use of NHS Number.
4. That the applicant was to discuss with the NIGB Office the Data Protection compliance aspects to the study.

Action: NIGB Office to inform applicant of Committee decision.

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

This application from NHS Northwest concerned the analysis of data relating to the same patient across various settings and interactions, in order to identify trends and to inform service improvements. Section 251 support was requested to access health records from a variety of sources, (eight datasets in total), including CDS, CCAD, PROMs and MINAP with a view to linkages being made.

This application was first considered at the November meeting where Members had expressed concern that consent had not been fully explored and agreed that due to the large amounts of required identifiers and linkages, that plans for consent should be actively pursued. It was also noted that service user involvement was poor and any resubmission should outline how this would be undertaken. Members felt that this was particularly important due to the wide ranging nature of the application.

Members agreed that this was a complex application; that the applicant had made significant attempts to address the previous queries, and were appreciative of the further detail provided. The Committee noted the intended purpose of the innovative programme; to help bring about better resource allocation and improve overall quality of care and treatment within healthcare services. Members also commented that from the information provided, it appeared the activity was already going ahead. The Committee were encouraged that the applicant had decided to seek section 251 and felt that it was important that the information was being shared on a secure legal basis.

Members discussed the possibility of consent and felt that this had not been fully explored within the application. They noted that the applicant specified that consent would be difficult to obtain but queried what evidence they had based this upon. Members noted that the PROMs data was fully consented but not for this purpose, and as patients who provided responses to the questionnaire were reassured that this would not be returned to their clinician, they queried whether this proposed activity would contradict this reassurance. Members noted the use of the Personal Demographics Service (PDS) and queried why this data could not be used to consent the cohort.

The Committee commented that it appeared that compliance with information governance standards had not been developed in tandem with all aspects of the activity, and reiterated that it was important for information governance to be considered at the outset of any project or activity, so as to avoid potential issues at a later date.

Members were mindful about the large amount of data that would be collected on each individual and for this reason felt that the purpose of the application needed to be explicit. Members agreed that the purposes of each activity within the main application were still unclear in terms of how the linkages would derive benefits for patients and the public. The lack of presentation of an evidence base around the benefits of linkage of confidential patient information made it difficult for the Committee to assess whether it was in the interests of improving patient care or in the public interest.

Overall the Committee were keen that the work outlined should proceed but felt that the issues identified needed to be fully explored before this could gain section 251 approval. Members agreed that an offer of a meeting should be extended to the applicants with the Chair and two Members of the Committee to attend. The intention of the meeting would be to discuss the legal aspects of the application, the evidence base for the benefits of the linkages, the merits of separating the application into several defined projects, the merit and feasibility of piloting specific aspects of the programme and the provision of advice on information governance aspects within the programme.

Action: NIGB Office to inform applicants of Committee decision.

c).Evaluation of service provisions for adolescents with eating disorders [ECC 6-06(l)/2009]

This application from King's College London aimed to explore and identify 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 make an amendment to the currently anonymous tracking sheet. The application outlined plans to add initials and date of birth on to the tracking sheet of those who had not consented/responded to the invitation to participate in order to maintain accurate tracking of cases and prevent duplicate invitations being sent. The date of birth was not to be used for any other purpose.

This application had been rejected at the November Committee meeting as the application outlined plans to retain data on non-responders and due to this Members felt that it would be overriding dissent if section 251 were given. The applicant had provided a response to these concerns and further justification why section 251 was required. This further justification was considered by Members.

Members considered the additional information on the purpose of maintaining accurate tracking information on eating disorder patients. They discussed that this additional information was key to the application and that there was a real importance in maintaining accurate numbers for the specified purpose.

The Committee discussed whether the purposes of ensuring that persons were not sent repeat invitations could be achieved by use of the NHS Number rather than additional identifiers. It was agreed that NHS Number would not be sufficient to track those service users that access both private as well as public healthcare, as private healthcare providers do not have access to the Personal Demographics Service to obtain NHS Number.

Members also assessed in detail the applicant's letter that set out why section 251 was not being requested to override dissent. Members noted that potential participants were asked for consent for the research team to access their clinical are notes via completing a form. If a signed consent form was received then the participant would be included and the researcher would access the case notes. The request for additional data items was solely to allow the applicant to accurately count non-responders/dissenters on the case lists and that the applicant would not be accessing case notes of this sub-cohort.

The Committee agreed that section 251 was not being sought to override dissent and therefore provided provisional approval to this study subject to satisfactory security arrangements.

Action: NIGB Office to inform applicant of Committee decision.

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

This application from the University of Southampton had initially applied for support under section 251 to examine the mortality and cancer incidence of a cohort who had been born in the village of Seascale to investigate whether there had been a continuing health disadvantage to them. The application had originally detailed gaining information from the Central Register, without seeking consent. The Committee previously agreed to provide support under section 251 to permit the applicants to trace the cohort so that consent could be obtained.

In response to the outcome letter the applicants wrote to query the condition that consent be sought after the initial tracing of the cohort. The applicants set out reasons justifying the impracticability of obtaining consent and the likelihood of non-response by the cohort.

Following discussions, it was agreed that Professor Mike Catchpole would contact the applicants to discuss the issues and report back to the Committee. The Committee were asked to consider the response from the applicant and reach a decision as to whether the original decision should be upheld in light of the new information.

Members agreed that this was an important study that had already produced valuable results, and that the value of future analyses was critically dependant on achieving a high level of ascertainment of the health status of the surviving members of the cohort.

Professor Mike Catchpole provided an update to the Committee arising from discussions with the applicant and noted in particular that the cohort had never been contacted about the study. Members noted the issues raised as to whether seeking consent would be reasonably practicable and agreed, in this specific instance, that due to the historical nature of the cohort there would be particular difficulties in this approach. However, Members noted that the provisions of the Data Protection Act must be complied with and therefore recommended that a suitable alternative approach would be to contact all individuals in the cohort via their GP, provide them with information about the study, and give them the opportunity to opt out of the study.

Members also raised an important ethical issue that is significant to most birth cohort studies, in that it was not possible to know whether any of the cohort were adopted and that they may also not be aware of their original birthplace. Members agreed that if there were members of the cohort who had been adopted they were likely to have been lost to follow up.

On balance, Members felt that the public interest of this study would be substantial and for that reason section 251 support could be provided and explicit consent would not need to be sought from the cohort. However this was subject to the condition that MRIS would be used to contact individuals via their GPs in order to inform them about the study and to provide the right to opt-out. Members agreed that the letter should be carefully worded to avoid undue alarm.

The study was provisionally approved subject to the following conditions:

1. A copy of the favourable opinion from the REC being provided to the NIGB Office.
2. A copy of the letter to be sent to the cohort being provided to the NIGB Office.

Action: NIGB Office to inform applicants of the Committee decision.

4. New applications for section 251 support

a) High dependency, high containment, difficult to manage inpatients (HICON) study ECC 1-04(a)/2010

This application from City University required section 251 approval to carry out a prospective study to investigate and identify problem behaviours that resulted in containment, and the motivation and reasoning of staff in containment strategy selection. The cohort consisted of all inpatients in East London Foundation NHS Trust who had been in receipt of high levels of containment in the two weeks previous to the study. Section 251 was required to carry out a case note review of 65 inpatients without consent.

Members agreed that this was an important study that would be of public benefit. Members noted that the case note review process would be carried out using specific tools, which would be unconsented, and that interviews with relevant staff members would be linked back to the

information collected in the case note review. Members agreed that it was important for the case note review and interviews to be contemporaneous so as to avoid the issue of recall bias. Members also discussed at length the difficulties of seeking consent from the cohort balanced against this issue, whilst respecting the rights of individuals to opt-out of the activity. In particular, Members were concerned to ensure that whilst the cohort could be difficult to consent that this in itself was not an adequate justification to provide section 251 support. Concerns were raised that if it was confirmed that if an individual did not have the capacity to consent then provisions under the Mental Capacity Act should be followed. Members then discussed the possible alternative arrangements to ensure the essential contemporaneous nature of the activity but concluded that due to the defined time period of the study, consent would render the study invalid.

Members noted that while there would be posters displayed on wards in order to inform staff that the study was going ahead, originally there had been no intention to provide the same fair processing information to patients. The Committee agreed that in order to comply with the Data Protection Act 1998, that similar arrangements should be made available to patients and these should include information on how to opt-out of the study.

Members discussed the issue of patient identifiability due to the extent of information to be collected and the combination of data items. Members noted that when publishing the results, extreme care would need to be taken to remove any possibility of patient identification, and were particularly concerned about inferential identification from published data items, due to the cohort being an unusual group and many admitted under “section” to a single named trust within such a defined period. For example, the possibility of the individual being identified by linkage with data held by the police might have serious implications. It was agreed that the applicants should consider the extent of data items required and clarify the information that would be published to provide assurance to the Committee. In order to address the issues over inferential risk of published data the Committee suggested that the development of an External Advisory Group would be a suitable option to monitor this and other issues involved in the sensitive nature of the study.

Members expressed concern over the abbreviated title of the study and were of the view that in terms of communicating the study to patients it could potentially be a provocative title and the applicants should be mindful of the implications of this.

Members noted that, initially, patient and service user involvement had not been sufficient but that following correspondence with the NIGB Office the applicant had indicated a willingness to pursue this further, which the Committee welcomed.

Based upon a balance of the earlier considerations, Members agreed to provisionally approve this study due to the public benefit and the lack of opportunity to seek consent due to the methodology being used. This study was approved subject to the following conditions:

1. A copy of the favourable opinion from the REC being provided to the NIGB Office.
2. The establishment of an External Advisory Group to oversee publication of results with particular focus on the inferential identification of the cohort.
3. Information about the study to be readily available to the patients including an easy option to permit opt-out.
4. Confirmation whether any of the above requirements necessitated a substantial amendment to be made to the REC, and if so, a copy of the favourable opinion to be provided to the NIGB Office.
5. Consideration of the inference that could be made following publication of the results and a view on how this would be managed in discussion with the NIGB Office.

Action: NIGB Office to inform applicant of Committee decision.

b) Evaluating the age extension of the NHS Breast Screening programme in England ECC 1-04(b)/2010

The University of Oxford required section 251 support to carry out an evaluation of the benefits of increasing the age range of the NHS Breast Screening Programme from 50-70 to 47-73. In order to do so the application proposed access to the National Breast Screening Service (NBSS) systems for data on women aged 47-49 and 71-73 to allow the cohort (estimated to be around 1.1 million) to be flagged for cancer and mortality on the Central Register in order to assess the outcome.

The Committed were supportive of this application, considered it to be a clearly constructed and the reasons for requested identifiers had been appropriately justified. Members were particularly mindful of the importance of this study in relation to the wider public interest.

Members were concerned that an opportunity for consent for some of the cohort was being missed when the cohort attended for screening. However it was noted that these women would be provided with an information sheet with details of the study and that attendance at screening would amount to implied consent. Members discussed the fact that those randomised out of the study would not be made aware of the study at the current point in time and considered whether it would be appropriate to provide section 251 for this sub-cohort.

Members noted that this was a study that aimed to evaluate the effectiveness of extending the age period for offering screening to women, and that this age extension would be phased in to the whole population over the next few years, at which point all women would be provided with the relevant information and given the option to opt-out of the screening programme.

Upon balance, Members agreed that the substantial public interest provided sufficient justification to provide section 251 support to the whole evaluation study as all women would be provided with information about the study in the future. Members also noted that this was a one-off opportunity for the study to be carried out.

This study was provisionally approved subject to satisfactory security arrangements.

Action: NIGB Office to inform applicant of Committee decision.

c) The Epidemiology of Cycle Related Injuries: Identification of modifiable risk factors for severe road traffic related injury in cyclists ECC 1-04(c)/2010

This application from the University of Leicester aimed to determine basic patterns, causes and risk factors associated with severe and fatal cycle injuries in Leicestershire. Section 251 support was required in order to allow a student researcher access to emergency department data and manually review patient records to validate patient demographic, injury severity and outcomes; matching the data to STATS19 data on road accidents involving cyclists.

Members noted that this application had received an unfavourable opinion from the REC and that the applicant was intending to resubmit to the REC. Members initially discussed whether this would fit within a medical purpose due to the stated aims of the study, but agreed that it would fall within the definition of preventative medicine to support the wider public health.

Members discussed that the applicant was a BSc student who would be working under the supervision of a clinician within the emergency department of the Leicester Royal Infirmary. Members discussed at length the implications this had and whether the student would require

section 251 support to gain access to this information, as General Medical Council guidance stated that student doctors have the same duty of care as qualified doctors and the applicant would be working under a clinician who worked in the emergency department. However Members noted that the student would not have been directly responsible for the care of any of the cohort as this was a retrospective study, and also noted that access was required to most emergency department records on the dates identified from STATS19 data in order to identify the correct individual. Therefore the disclosure was much wider than just the records of those identified by the STATS19 data. Members agreed that the student would require section 251 to identify, link to and extract the records as they were not part of the direct clinical care team engaged in the care and treatment of the cohort.

The Committee raised more general concerns about the validation and linking of emergency department records to anonymised STATS19 data. Whilst it was noted that the data would be re-anonymised after validating and linkages had taken place, Members raised concerns about the risk of constructing a profile of an individual from these two sets of data and about increasing the identifiability of the datasets. For instance there were concerns that the sensitive data regarding culpability of an accident could become known from the data validation between the two datasets and therefore any analysis of the data should only be carried out once the data have been anonymised. Members also discussed whether it was an issue for STATS19 data to be rendered identifiable and whether it should be released for these purposes. The Committee felt that the above issues provided further reasons for the importance of exploring consent within the cohort.

In examining whether consent had been explored sufficiently, Members noted that reasons provided within the application for not seeking consent were administrative burdens, difficulty tracing the cohort, inaccuracy of cohort contact details, disproportionate and unnecessary distress that may be caused in contacting families, unwillingness of GP practices to cooperate in the consent process and potential selection bias. However the Committee noted that the cohort size was relatively small in number and considered that a pilot to test consent could be attempted in order to provide evidence to the stated reasons for not seeking consent.

As such, Members concluded that consent might be practicable and advised that if concerns with regard to tracing the cohort were evidenced after making attempts to seek consent, then the applicant could make a further application to the Committee in order to seek access to cohort contact details via the Personal Demographic Service or for access to deceased persons' records.

Action: NIGB Office to inform applicant of Committee decision

d) Evaluation of functional capacity testing in cardiovascular patients ECC 1-04(e)/2010

Support under section 251 was requested by the University of Essex in order to carry out a retrospective case note review to determine normal values of functional capacity in cardiovascular disease patients prior to and after receiving cardiac rehabilitation. The application proposed examining around 2500 patient case notes in four trusts over a two year period.

In considering this application the Committee raised a number of concerns. In particular it was noted that the primary reason stated for not pursuing consent was due to administrative burdens and the lack of financial resource to pay the direct clinical care staff to carry out the extraction and anonymisation of the data themselves. The application also stated that Trusts would be reluctant to authorise their staff to carry out the work. It was not clear to Members why date of birth was to be retained.

Members discussed that use of section 251 in order to overcome administrative burden and concluded that it could not be used to overcome resource or funding issues. Whilst Members considered that the purpose of the study was important they were not provided with sufficient evidence to justify why consent was not feasible, and were of the opinion that it would be.

Members were also concerned about the lack of patient involvement in relation to the development of the study.

The Committee was therefore unable to approve this application due to the reasons stated above and recommended that a consent approach be pursued.

Action: NIGB Office to inform the applicant of Committee decision.

5. Items for consideration

a) International Cancer Benchmarking Project [ECC 1-05(a)/2010]

This item consisted of a paper setting out details of the activity and a supporting paper that provided justification for the various data items. Members noted that this paper had originally been submitted for Chair's action but due to the issues it had raised, this had not been deemed suitable to be considered under Chair's action. On an exceptional basis, it had been agreed for this paper to be placed as a late item on the agenda as it was cited as extremely urgent, even though it had been received a significant period of time after the formal submission deadline. In the event, the urgency receded. Members also noted that the applicant had provided further responses to queries but due to the short timescales to provide this response, there had not been sufficient time to distribute these to Members and therefore these comments were summarised at the meeting.

This paper outlined an activity to examine survival for five common cancers (breast, colon, rectum, lung and ovary) in 12 jurisdictions (England, Wales and Northern Ireland, plus Australia (New South Wales and Victoria), Canada (Alberta, British Columbia, Manitoba and Ontario), Denmark, Norway and Sweden). The data sets included adults (aged 15-99) diagnosed during the period 1995-2007, with follow-up to 31 December 2007 or 2008. The paper also provided justification for use of full dates of birth, diagnoses and death.

Members agreed there was a strong public interest in the study being undertaken and noted that it was important to be able to benchmark cancer activity against other countries. However, Members raised a number of concerns over issues to be taken into consideration if data was to be processed abroad. Members noted that jurisdictional issues should not be a barrier to high-quality research, but that these issues should be fully explored in an application. Members discussed the remit of section 251 and noted that it applied to data generated in England and Wales, but that the Regulations were not specific on jurisdictional issues. It was requested that a short paper be presented to the Committee on section 251 and international jurisdictions.

Action: NIGB IG Lead to provide paper to the Committee on jurisdiction of section 251

Members queried whether the calculations of comparative survival times could be calculated by aggregation of the individual records in each of the Cancer Registries who already held specific support for processing of cancer data. Inconsistencies between methodologies of registries which already had approvals for processing, did not seem to be an acceptable reason for using section 251. Statistical reasons (the need to construct confidence intervals) may prevail for rare cancers. However it was noted that for common cancers, aggregation

should be adequate. They were mindful that good quality data would be required and that individual survival times were crucial. However they indicated that they would require further explanation of the chosen methodology and alternatives before a decision could be reached.

Members also noted that the paper did not cover all sections that would have been explained if a section 251 application form had been used. For example, there were no security arrangements or Data Protection considerations detailed in the paper, and the further information required to allow the Committee to take an evidenced decision had been requested separately via a set of questions. Members agreed that in terms of proper process, any applicant wishing to seek support under section 251 should fully complete an application form or seek advice from the NIGB Office on the appropriate process to submit a request to the Committee.

Members also expressed concern about the exact scope and purposes of the application, as it appeared that the applicant was requesting that the Committee provide reassurance to the other jurisdictions that were to send their data to the applicant for this activity, that the security and confidentiality arrangements were satisfactory. Members discussed the remit of section 251 and therefore required greater clarity on precisely what the applicant required in terms of approval under section 251.

Members noted that the activity would be led by a previous applicant and there would be strong links to that applicant's previous application [PIAG 1-05(c)/2007]. However Members agreed that each application should be considered upon its own merits and therefore a detailed application should be submitted, taking fully into consideration all the Data Protection, jurisdictional and security arrangements. It was also requested that the applicant set out clearly the methodology chosen and explain why this would be necessary over alternatives. This would enable Members to have all details within one application and allow a proper assessment of the facts.

As such, whilst mindful of the importance of the study, Members agreed that the applicant should submit a detailed application, taking fully into consideration the points made above.

Action: NIGB Office to inform applicant of Committee decision.

b) Iron deficiency anaemia and delayed diagnosis of colorectal cancer [PIAG 4-05(k)/2007] – outcome of feasibility report

This application was originally considered by the Patient Information Advisory Group (PIAG) in 2007. At this time, PIAG had provided section 251 support to carry out the activity for a pilot study in one practice, and had requested that a feasibility study to consent the cohort be carried out before considering whether this study could be extended into other practices. Once the feasibility study had been carried out, PIAG had indicated that a further meeting should be scheduled to discuss the way forward in relation to the wider study. Members were informed that a meeting had taken place with the NIGB Office and the applicants had discussed the report and provided general context to the study. It had been agreed that the report would be placed on the agenda at the meeting for the Committee to identify and recommend the next steps.

The Committee commended the applicant for carrying out the pilot study into consent and appreciated that it provided a detailed review on consent within the context of the activity, and an evidence base with which to discuss the next steps. Members were also mindful of the high public interest outcome of this study.

The Committee noted that a significant proportion of people had consented to the activity (63%), and that 7.8% had actively dissented and Members emphasised that section 251 could not be used to override active dissent. Members also discussed the importance of providing fair processing information to all participants.

Members noted that a significant proportion of the cohort in certain age groups had consented as opposed to other age groups, and discussed the implications of this on the study Members raised the point that therefore this would lead to a selection bias which would mean that the outcomes from the study could not be extrapolated to the whole population and queried the impact of this upon the study. Members discussed the importance of full ascertainment in achieving the aims of this study and whether the overall purpose could be achieved with consent and therefore adjusting for the impact of bias on the study. It was noted that the study was about the care of the patients rather than the epidemiology of the disease and therefore Members queried if the aims could still be fulfilled as the demographic data might not be as important for this aim. However views were raised that when determining access to care, demographic data would be important and the study might not be valid if only receiving information from one age group. Members felt that the applicant should explore whether the bias would render the study invalid. It was also queried whether it would be possible to carry out this study any other way so as to avoid any bias.

A question was also raised about the need for further linkage rather than using the anonymised THIN dataset.

Due to the number of issues raised, especially around the area of bias, members felt that it would be helpful for a meeting to be arranged between the applicant, the Chair and two other Members of the Committee who were epidemiologists. This meeting would provide an opportunity to discuss further the outcomes of the feasibility study and the impact of this on the wider study.

Action: NIGB Office to inform applicant of Committee decision.

c. Format of Future Meetings [ECC 1-05(c)/2010]

Members were presented with a paper outlining suggestions to enable the Committee to deal with the increased number of applications that it was had been receiving. Members were given the option of two day meetings, improved fast track processes allowing a greater number of applications to be considered outside of Committee meetings or an increased amount of meetings per year. The benefits and disadvantages to each approach were discussed.

As a whole, Members felt that two day meetings would not be the most practical way to solve the issue due to availability of Members and ensuring that meetings would be quorate. They were in favour of an improved fast track process and suggested that teleconferences and discussion boards would provide a way to allow a debate to take place within the process. Members were also in favour of having an increased number of meetings per year.

Members also commented that they had found it helpful and productive to have applicants attend meetings and suggested that this could be a way forward in future, subject to the caveat that it would not be feasible to invite all applicants to attend. A view was raised that this could be achieved by having a smaller number of members meet with the applicant and then feedback in the full Committee meeting and that applicants should be invited only when resubmitting or when the application raised particularly complex concerns or was of national significance.

Members were asked to share their feedback from proposals formally with the NIGB Office so that these views could be developed further.

Action: Members to share views on the format of future meetings with NIGB Office.

6. Any other business

No further business was discussed.

7. 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