Meeting held on Tuesday 28 September

Present

Members: Dr Andrew Harris (Chair), Mrs Pauline Brown, Dr Tony Calland, Dr Mike Catchpole (to item 4 H), Dr Tricia Cresswell, Dr Fiona Douglas, Ms Stephanie Ellis, Professor Sir Denis Pereira Gray, Mr Michael Hake, Ms Sue Parroy, Dr Mark Taylor.

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

1. Welcome and apologies

Apologies were received from Dr Patrick Coyle, Professor Carol Dezateux, Ms Ros Levenson, Professor Roy McClelland and Mr Terence Wiseman. The chair thanked Professor Carol Dezateux for her written comments on the following items; ECC 7-03(a)/2010, ECC 7-03(b)/2010, ECC 7-04(e)/2010, ECC 7-04(g)/2010 and ECC 7-04(j)/2010.

Members were informed that Ms Ros Levenson had resigned from the Ethics and Confidentiality Committee, due to a professional conflict of interest and that due to other work commitments Professor Roy McClelland did not intend to continue with membership past the end of the year.

Members were informed that the advert for the recruitment of ECC members would be publicised shortly, following the publication of the Government's Arms Length body Review in October. It was announced in the Government's Arms Length Body Review that the statutory role of the NIGB would be transferred to the Care Quality Commission in due course. The important role of the Ethics and Confidentiality Committee would be maintained until at least 31st December 2011 and at a future date be transferred to a proposed research regulatory body. The Department of Health had approved recruitment of new members to replace retiring members in order to maintain continuity and support the Section 251 approvals process during this transition period. Members noted that it would be important to retain the link to Northern Ireland when recruiting.

2. Minutes of last meeting [ECC 6-02/2010] and matters arising

The minutes from the 27 July meeting were approved subject to minor amendments.

2a. ECC Chair's Report [ECC 7-02(a)/2010]

The Chair provided an update on the NIGB meeting attended on 8 September 2010. This report covered the following aspects:

- The proposed framework for honest brokers
- Changes to version 8 of the Information Governance toolkit
- Research Database Working Group
- Professor Greenhalgh's evaluation of the Summary Care Record and HealthSpace Programme.
- Care Quality Commission's Code of Practice

The minutes of the NIGB meeting would be made available on the NIGB website.

2b. DMsG Chair's Report [ECC 7-02(b)/2010]

The DMsG Chair provided a report detailing all applications approved since the last ECC meeting and applications that had been considered at the DMsG meeting on 20 July 2010.

The minutes of the DMsG meeting would be made available on the NIGB website.

2c. NIGB Office Report [ECC 7-02(c)/2010]

DMsG

Members were informed that the Database Monitoring sub-Group of the ECC would formally transfer to be managed by the NHS Information Centre (NHS IC) from the end of September 2010. The NIGB Office would be liaising with the NHS IC to ensure a suitable transfer. It had been originally planned that the DMsG would become a sub-group within the Independent Advisory Board (IAB) structure. However, due to the Arm's Length Body review and efficiency measures and restrictions of the new Government which have impacted on the establishment of the IAB, alternative separate arrangements had been made in the interim.

NHS Care Record Guarantee

Members were informed that the NIGB Office was in the process of reviewing the NHS Care Record Guarantee. The main commitments in the Guarantee would remain largely the same with some potential improvements to language. However, a more significant change to the text was required to reflect that the National Programme for IT was now devolved to a more local level and it was no longer possible to guarantee some elements of the Programme in every locality.

Research Database Working Group

The report of the Research Database Working Group was discussed at the NIGB meeting on the 8 September. The NIGB concluded that it was an interesting and comprehensive report but that implementation partially lay with other bodies as well as the NIGB. It was agreed that a copy of the report would be provided to the AMS review of research regulation and that a small group of NIGB Members would meet to decide which of the recommendations were for the ECC or NIGB to take forward and which were for other bodies.

ECC Application Database

Members were informed that the NIGB Office had been working with IT suppliers and IRAS to develop the ECC Applications Database. The database was likely to go live in November and Members would be able to access applications through the web-based system.

Changes to current applications – NHS Information Centre

Members were informed that a number of changes have taken place in relation to the NHS Information Centres activities that have support under section 251.

1. A condition of approval provided to the Department for Transport [PIAG 1-05 (g) 2007] was for a move to be made for the linkages between HES and STATS19 data to be carried out by the NHS IC. Development work on this aspect was now taking place and involved working with the NIGB Office to establish clarity of data controller arrangements, data flows and satisfactory assessment of security arrangements

2. The NHS IC had notified the NIGB Office that they were now sole data controllers for the SUS application, rather than joint data controllers with the DH. Data flows and security arrangements have remained the same. However, it had been identified that a third party was receiving data prior to it flowing into SUS; and the NHS IC had been asked to clarify the situation with a view to ensuring the application correctly reflected the data flows.

3. The NHS IC had notified the NIGB Office of their requirement to extend their capacity and capability to provide linkage services on HES, and had sought to extend their processing capacity to include their in-house IT environment, referred to as the Data Management Environment. It had been confirmed that should they be asked to carry out linkages on patient identifiable data that they did not currently receive, the applicant would be required to have consent or support under section 251.

UPDATES ON PREVIOUS APPLICATIONS

Health Protection Agency (HPA) annual review.

A meeting had taken place with the NIGB Office and the HPA following the outcome from the July Committee meeting. The HPA intended to submit a revised annual review for the December meeting. Public Health Wales had initially been removed from the HPA annual review, however, further discussions identified that they would continue to be covered within the HPA's specific support, and PHW would submit an individual application towards the end of the financial year.

Cam-Can [ECC 6-05 (e) 2010]

This application had been provisionally approved in July; however, the Committee did not approve the purpose of the researchers visiting potential participants at home if they did not respond to the request to participate. As this aspect had been approved by the REC, members requested that this was reconsidered. The responses from the applicant were reviewed by the Chair and Members who originally assessed the application. Following detailed written rationales, the decision was exceptionally taken to approve this aspect of the application. The reason for this decision was that clear information was provided via the GP, the participant had the choice to opt in to the research or reject the visit on more than one occasion, the researchers were highly experienced and had successfully used this approach before, the person visiting was a health professional with training in handling the elderly with cognitive impairment and the loss of many of this client group would be a serious compromise to the study. It was agreed that this was a proportionate and reasonable approach.

ECC 6-05 (f)/2010 - A clinical, economic and operational evaluation of the pilot Women's Enhanced Medium Secure Services (WEMSS)

A meeting regarding this application took place between Professor Carol Dezateux, Dr Fiona Douglas, the applicant and the NIGB Office in follow-up to the outcome from the July meeting. At the July meeting, the Committee had been unable to approve the application for a number of reasons; the key one being that it appeared that support under section 251 would be used to override explicit dissent. Additionally, questions were raised about the rationale for requesting the specified identifiers, scope of the activity, degree of anonymisation and extent to which the local teams could extract the information.

The subsequent meeting and discussions clarified a number of issues and provided reassurance over the activity. In particular, it was noted that a key consideration that justified support under section 251 was that there was an undisputed requirement for independent collection of data to maintain validity of results. As such, it was agreed that there was no other practicable alternative to accessing patient identifiable data. The group provided a recommendation of approval to the Chair, which was accepted, subject to the conditions that the original application form would be revised to

reflect the clarifications and additional security measures to protect against the risk of inferential identification, and that any complaints that might arise would be reported in the next annual review.

AMENDMENTS AND EXTENSIONS

Investigating cancer in the north of England and defining survivorship [ECC 1-06(h)/2009]

This amendment to the above study outlined four changes to the existing section 251 approval:

1) Extending the study from a regional to a national study.
2) Reducing the number of cancer sites investigated from five (breast, colorectal, lung, prostate, and gynaecological cancers) to just two (colorectal and haematological cancers, which includes Hodgkin disease and multiple myeloma).
3) To add a healthy control group in order to inform phase two of the study, to link datasets and map patients NHS footprint.
4) To link data with GPRD data in order to gain a more informed picture of the patients time within the NHS.

Members were informed that all linkages would take place within Northern and Yorkshire Cancer Registry and Information Service (NYCRIS) and that all identifiers would be destroyed after linkage had taken place. Members agreed to approve this amendment subject to the confirmation of satisfactory security arrangements and the submission of an annual review.

PIAG 1-05(FT1)/2007 Development and validation of risk-adjusted outcomes for systems of emergency medical care (DAVROS)

This amendment proposed a change to phase six of the DAVROS study. The original application stated that case reviews would take place by an expert panel in phase six of the study, in order to validate discrepancies in the outcomes predicted by the model. It was now confirmed that the case reviews would take place within the local care teams, meaning that no patient identifiable data would be disclosed at this phase. As this involved no additional disclosure this was not reviewed by Members.

PIAG 4-08(b)/2003 National Confidential Enquiry into Patient Outcome and Death (NCEPOD)

The National Confidential Enquiry are required to report any additional studies that they carry out under their section 251 support. This extension was for the Cardiac Arrest Study. The aim of this study was to describe variability and identify remediable factors in the process of care of adult patients who receive resuscitation in an in-hospital setting. This was approved via Chair action.

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

This amendment proposed to link anonymised ICON and ICNARC databases using the ICNARC number, which was routinely collected as part of the ICON dataset. It was confirmed that identifiable data would be removed from both datasets before linkage took place, that no identifiable data from ICNARC would be available to the ICON study and that the data would only be used in an anonymised aggregated format.

FAST TRACK APPLICATIONS

Language used to convey doubt and certainty in radiology projects [ECC 7-02(FT1)/2010

This application was assessed by the Chair and a smaller number of Committee Members as it fell within the fast track criteria "applications where applicants are only accessing data on site to extract an anonymised/ effectively pseudonymised dataset".

This application set out the purpose of investigating language used by radiologists in their reports. As radiology reports were the main method by which radiologists communicate their diagnoses to clinicians, this was where potentially problems could arise and it was indicated that the study had the potential to help reduce errors in patient treatment by improving communication between radiologists and clinicians. Section 251 support was sought to carry out this retrospective study through accessing the radiology information system to access radiology reports that had been written within the previous twelve months. A randomised selection of 100 reports from each author would be accessed. These reports would subsequently be anonymised on-site before transferring the anonymised information back to the researcher's institution.

Members considered this application to pose a low threat to privacy, and were generally content with the arrangements. They raised the point that if there is a possibility of any discovered errors in reporting that have a clinical significance, then this eventuality should be considered at the outset of the activity and a mechanism put into place. This application was approved, subject to this condition and satisfactory security arrangements.

European Urban Health Indicators System Part Two (EUROURHIS 2): Urban Health Monitoring and Analysis System to Inform Policy ECC 7-02 (FT2)/2010

This application was processed under fast track criteria 9: Applications to identify a cohort of patients in order to seek their consent where the inclusion criteria only includes administrative/ demographic data & excluding both small & very large numbers. Access would need to be limited to the minimum information necessary to identify the cohort, prior to consent being obtained.

This application set out the purpose of studying trends in population health for urban areas across nine EU countries. This population based survey set out to query whether it would be possible to obtain information on urban health indicators to produce tools for policy makers at local, national and international level. The survey period would last 8 weeks and requested support under section 251 to permit access to NHAIS in order to obtain name, GP registration, date of birth, full postcode, gender and telephone number. The data was required for the sampling frame to be able to stratify by age and gender. It was noted that all partners would be using similar population registers and therefore it was considered essential to use the Exeter system so as to allow comparability with the other partners.

This application was approved, subject to the assurance that checks for suitability to participate would be carried out by the GPs, the letter should make explicit that the participant was not required to take part, and that non-response would lead to a home visit. The participant should also be permitted the facility to opt-out via a telephone call and not just via letter. Additionally, the researcher must be trained to ensure no coercion would be placed on the participant, and be familiar with capacity requirements under the Mental Capacity Act.

Care in the last days of life: aspects of decision making ECC 7-02 (FT3) 2010

This application from the University of Nottingham requested support under section 251 to permit access to medical records to extract information, in order to identify decision-making surrounding the application of palliative sedation that continues until death. The study consisted of two phases; phase one involved interviews with healthcare professionals (all references to this aspect are excluded from s251), and an audit of medical notes in relation to adults who died of cancer within a 12 week period. These would be obtained from hospices, hospitals and those under the care of a

GP. Phase two would involve a review of deceased person's medical notes to identify whether, why and how palliative sedation was used. Consultants/GPs would identify cases, and information would be extracted on-site by the researchers.

Members were persuaded that there was no other practicable alternative to obtain the relevant information, and agreed that there would be a high public interest in the outcomes. As such, this application was approved.

Evaluating the needs of patients living with chronic cancer: interviews and survey development ECC 7-02 (FT4)/2010

This application from University of Leeds Teaching Hospitals outlined the purpose of examining everyday challenges that patients living with chronic cancer face and the support services that they require in order to improve understanding of patients needs. This would be achieved by interviewing patients and health professionals. A secondary aim would be to develop and validate a patient needs survey so that patient needs could be examined across the UK. The application required section 251 support in order to allow researchers to have limited access to patient electronic records prior to consent to identify eligible patients, to make first contact and subsequently to obtain consent for study participation.

As this application followed the same methodology and was from the same team of researchers as a previously approved application, ECC 4-15 (c)/2009: Routine assessment of symptoms and functioning in cancer patients, it was agreed that this could be considered via fast track.
This application was approved.

ITEMS FOR CONSIDERATION

3a. National Clinical Audit Support Programme (NCASP) Review (ECC 7-03(a)/2010)

This application from the NHS Information Centre (NHS IC) was approved in March 2009 for a 4 month period. It was reviewed again in July 2009 and support provided for a further 8 moths, to permit the NHS IC sufficient time to work on developing an exit strategy from section 251 support, opt-out provisions, to develop further some assertions about engaging with disenfranchised groups, and to provide further information on how patients would be involved in the activity.

At the March 2010 meeting Members had been informed that the intention was for a number of the cardiac audits included within the NCASP approval to move to a different data processor (NICOR). Members requested that further progress needed to be made toward moving away from the reliance on section 251 support and had therefore requested that this submission provide a plan on how progress towards consent or pseudonymisation had been achieved for those audits where 100% ascertainment of NHS number had not been achieved. For those that had achieved 100% ascertainment of NHS number progress towards reducing the identifiability of data was requested.

Members welcomed the detailed report and discussed the content at length. Members noted that a consultation exercise had been carried out by the applicant around the feasibility of obtaining consent for the audits and agreed that a large amount of work would have gone into the exercising of this. The report detailed evidence of difficulty on a number of levels. In particular, it highlighted some cultural issues and administrative concerns around the seeking of consent. Members were mindful of some of the issues raised but noted that support under section 251 could not be used to overcome such issues. In addition, Members were surprised to see the extent of work carried out on this aspect as this had not been explicitly requested by the Committee; however they valued the aspects that the report highlighted.

The Committee agreed that consent was not reasonably practicable for such large numbers in terms of the overall NCASP audits; however Members expected that where consent could be obtained when there is reasonable opportunity to do so, and then consent should be taken.

Ultimately, in line with the Data Protection Act fair processing requirement, the Committee would expect patients to be informed of national audit activity, such as making relevant leaflets available at a local level. These should contain significant detail about the benefits of audit as well as the transparency about safeguards.

Members discussed that they had expected to see significantly more detail placed on reducing the identifiability of data where there was 100% NHS Number, and for those audits where 100% NHS Number ascertainment had not been achieved and what steps would be taken to manage this. Therefore, whilst the activity to seek views on explicit patient consent added weight to the view that consent was not feasible at certain points, it had not explicitly addressed what had been requested and could have benefitted from focusing upon the strengths of pseudonymisation as an exit strategy.

Members were informed that six audits were expected to transfer to University College London and that data relating to the cardiac audits could not be transferred until UCL had full operational approval under section 251, and that it needed to be ensured that the NHS IC's approval covered the associated onward disclosure. It was noted that the approval did not currently did not permit the onward transfer for this purpose, and that this could be managed via the NIGB Office when the arrangements meant that it was feasible to do so. As such Members agreed that an extension for the six audits would be provided until March 2011.

Members discussed the remaining audits and noted that they would expect to see significant steps taken towards the pseudonymisation of data in those audits which had obtained almost 100% NHS Number. Members advised that the audits should be separated out and presented individually. The Committee would expect to review the purposes of each audit, identifiers required, linkages and an assessment of each item to see if identifiability could be reduced, along with the reasons as to why this was not possible for each item. Members requested that this be completed in full by April 2012 and that an interim progress report should be provided to the Committee at the 28 July 2011 meeting.

Members noted that whilst the NHS Number was an administrative number it could permit linkage to far more identifiable data and therefore suggested that the applicant investigate the feasibility of developing a protocol on how to manage this aspect appropriately which could then be applied to all audits.

Members agreed that the audits could be approved under section 251 until 31 March 2011, subject to the following specific and standard conditions:

1. Detail of the role and input of the NHS IC to assist information about national clinical audit to be provided at a local level.
2. For audits where NHS Number was not complete, specification as to how a strategy would be put into place to obtain this.
3. For audits where NHS Number was almost or fully complete, to set out detailed steps of how identifiers could be reduced so that a pseudonymisation approach could be pursued as an exit strategy from section 251. These could be submitted on an incremental basis, preferably in suites, and this should be discussed further with the NIGB Office.
4. Conditions 2 and 3 above should be completed by April 2012 at the latest.
5. A focused report should provide specific updates on progress on conditions 1-3, this report was to be submitted to the Committee by 24 June 2011.

Action: NIGB Office to inform applicant of Committee decision.

Members additionally raised concerns about the perception of what it meant to obtain consent to clinicians and felt that this had been over complicated by being perceived as requiring an overly legalistic method of consent. Members agreed that consent should be managed as a more simplistic method of talking to patients and explaining what was going to happen to their data, along with the potential benefits of those uses. Members discussed the benefits of simplifying the

way clinicians thought about consent and by doing so felt that consent may become more realistic and practical.

3b. Record linkage in ALSPAC – non-responders (PEARL project) (ECC 7-03(b)/2010)

This paper requested the advice of the Committee on the collection of data on non-responders to consent requests for the collection and linkage of datasets. The applicant intended to write to the eligible cohort, follow-up with postal reminders and carry out home visits if necessary. The purpose of the intended PEARL project data collection would be to enable linkage between health, education, benefits and earnings and police records; after the linkage had been carried out the data would subsequently be anonymised to the research team.

It was noted that the Secure Anonymised Information Linkage (SAIL) database paper had been used to support the proposed opt out method and Dr Tony Calland, who was a member of the Information Governance Board for the SAIL database noted that further advice could be taken from SAIL when carrying out this work.

Members firstly commented on the important activities that ALSPAC had carried out, and understood that it had lead to a number of benefits. They also agreed that ongoing engagement appeared to be well handled and to be recommended as a model, and welcomed the request for advice.

In assessing the detail of the paper, Members understood that the intention was to seek consent from the cohort originally recruited to invite them to participate in PEARL. Members strongly welcomed the opt-in approach and thought this to be entirely appropriate considering the sensitive nature of the data linkages. Members discussed that it was difficult to know peoples intentions when non-responding and did not think it appropriate to assume that those who had consented to take part originally would be happy for their data to be used in this way if they did not respond. The Committee also agreed this to be an appropriate approach as it was not clear what the mechanisms were to access other data sources without this consent being in place. However, as access to non-medical data falls outside of section 251, members did not continue discussion with this aspect further, aside from confirming that support under section 251 would not authorise disclosure to other data sources outside of NHS-generated healthcare.

Members understood that the proposal was to write out to the original cohort of 14,000, plus an estimated 6,000 children who had been born in Avon but had not taken part initially. The paper indicated that these 6,000 had not been invited rather than refusing to participate, although members could not locate any information to support this aspect. It appeared that both groups were to be written to with the same information.

Members requested further information about the practicalities of tracing and contacting those who had not been recruited since pregnancy/birth. Members thought further information was required about tracing, what information was currently held about the 6,000 and how deaths and other reasons for not contacting the cohort would be identifier. Members also requested information about why the sub-cohort had not been approached for consent until this time. Members were of the view that this further information would allow them to make an informed decision and judge whether the 6,000 may need a different approach.

Additionally members discussed that they would expect to see the process of linkage to be more clearly defined to show the flows of identifiable data and how the linkages would actually occur. However, it was accepted that the paper was a request for advice and that the linkages had not yet taken place.

As a whole, members supported the PEARL activity, but in line with the comments above, felt that further clarity was required to the smaller sub-cohort from whom consent had not been originally obtained, before proceeding to consider this aspect further. Members were therefore of the view that the activity should be carried out in relation to the 14,000 who are already in contact with

ALSPAC in line with the details specified in the paper, utilising an opt-in approach. Once the actual proportion of non-responders was known, then the applicant should return to the Committee for a decision to be taken in relation to non-responders. The Committee felt that this was essential in terms of providing evidence to support sensitive data linkages without explicit consent.

Action: NIGB Office to inform applicant of Committee comments.

4. NEW APPLICATIONS FOR SECTION 251 SUPPORT

4a. Research Capability Programme – Honest Broker Service [ECC 7-04(a)/2010]

This application was for section 251 support in order for the Research Capability Programme of the Department of Health to pilot the Health Research Support Service (HRSS). This would enable the applicant to act as an honest broker through acquiring clinical, demographic and lifestyle data from data sources that routinely collected data. Specific items of data would be processed by the HRSS in order to achieve the purposes set out in the pilot studies. It was noted that the principal aim of this application was to test the capabilities of the HRSS with a view to identifying learning and refining future activities and that learning from this pilot would be fed back to the Committee in due course. This would then be used to match and link to other data sources, depending upon the nature of the study. The data would then be shared with the researcher once it had been pseudonymised using two keys. The service intended to provide the required linked data whilst protecting patient confidentiality.

Members welcomed the attendance of Peter Knight and Kerrie Williams from the Research Capability Programme on the 27 September. Members found this to be an extremely helpful and useful session and were of the view that this was of particular benefit in aiding Committee understanding of the overall pilot application. Following the meeting, Members discussed the key issues and provided a recommendation to the Committee.

As a whole, members were broadly satisfied with the application form, and the details of the studies to which anonymised data would be disclosed. They found the information to be clearly laid out, detailed and proportionate, and strongly welcomed this application as the future long term benefits would be significant. Members praised the applicant for the significant user involvement that had been carried out. They also appreciated that the applicant had undertaken considerable engagement with the NIGB Office and noted that this had had benefit when producing the application.

Members discussed the intention to test opt-out; Members were surprised to note that in testing consent via the GP practices, there appeared to be no facility to permit patients to opt out of their identifiable data flowing into the HRSS. Members were of the view that a pilot should be carried out to cover opt-out of the whole pilot activity, rather than just contact for research. They thought that suitable documentation should be provided to the cohort, and arrangements as to how this would be managed should be provided back to the NIGB Office. Members also considered the practicalities as to who would send out the relevant documentation to the cohort, and queried whether it would be feasible to resource the practice to send out letters in the first place so as to inform the cohort.

In conclusion, members agreed to recommend provisional support under section 251 to the pilot HRSS in relation to the five studies contained within the document. This support was given subject to the following standard and specific conditions of approval:

1. Confirmation of satisfactory security arrangements.
2. A pilot to be carried out to permit patients to opt-out of their identifiable data flowing into the HRSS, along with suitable documentation to be provided to the cohort. Copies of the relevant documentation and plan for approaching this should be provided to the NIGB Office by the applicant when available.

3. A favourable opinion letter from a Research Ethics Committee to be provided to the NIGB Office.
4. Any further disclosure of identifiable information to a third party would require an application to the Ethics and Confidentiality Committee and REC approval.

Action: NIGB Office to notify applicant of Committee decision.

4b. Association of Public Health Observatories – application for specific support [ECC 7-04(b)/2010]

This was a joint application from all nine Public Health Observatories for specific support under the Health Service (Control of Patient Information) Regulations 2002 SI No 1438, particularly that of section 3 "communicable disease and other risks to public health". This would enable the PHOs to collect data in relation to their public health activities. A meeting with the applicant had taken place on the 27th September with a smaller group of Members and this group fed back to the Committee at the meeting.

The Database Monitoring sub-Group of the NIGB had previously received applications for a full extract of HES data which contained patient identifiers from the PHOs. In previous years these extracts had been authorised through an agreement with the Department of Health that PHOs had "safe haven" status and could therefore receive HES extracts for their specific region. Members were informed that the NIGB had discussed what this status meant with the DH, and had been advised that this method of authorisation was no longer applicable, and therefore did not provide a secure basis in law for such use of patient identifiable information.

A way forward had been agreed with the NHS IC at the time of the PHO request for a full extract of HES data for 2008-09 to allow the release of data in that application, without the necessary section 251 approval as a temporary expedient given the low level risk to patient confidentiality and that it was required urgently. However it was agreed that a secure legal basis would be required for future extracts and therefore an application for section 251 support was made.

Discussion with the applicant had identified that Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002, as originally drafted, had not necessarily taken into account the evolving nature of public health since their establishment. Members acknowledged that it would stretch the boundaries of the current regulations to bring all of the activities contained within the application within the remit of Regulation 3. The Regulation as originally drafted concerned communicable disease and chemical/biological hazards, and members of the Committee were of the view that PHO activities were not consistent with the current drafting.

In assessing the detail of the application, members considered whether it would be more appropriate, due to the nature of the functions, to consider the application under the class support mechanism. It appeared that the public health activities could fall clearly under class support four which allowed the use of patient identifiers to link patient identifiable data from more than one source.

Members also noted that was expected that the PHO functions would come within the forthcoming Public Health Service and it would be better to wait until the relevant organisational and legal changes had been finalised before pursuing specific support provided by the Regulations at this time.

Discussion also highlighted that the public health observatories were not individual legal entities in their own right, and neither was the Association of PHOs. The issue over this aspect was that support under section 251 could only be provided to a legally established body. The Committee recognised the importance and significance of the activities carried out by the PHOs, and were keen to identify a suitable way forward. It was suggested that a host organisation could make an application on behalf of the PHOs so as to manage this legal barrier, and in doing so would take on the responsibility and risks surrounding disclosures and information sharing.

Once an appropriate host organisation was identified members would welcome an application to seek class support. Members recommended that the following should be taken into account when submitting the application:

1. A host organisation was to be identified.
2. That the application would need to be more specific and detailed in terms of data flows, purposes and items required so that the scope for which section 251 support was required was clearly set out.
3. A core dataset should be identified that would be in common use within all observatories.
4. Consideration should be taken over whether it would be appropriate for a third party, such as the NHS IC, to provide an equivalent of an "honest broker" service to carry out the linkages and then to provide the observatories with a set of de-identified data relevant to the core functions of each PHO.
5. The Committee advised that a resubmission should establish the individual activities that each PHO carried out and that for each of these activities it should be made clear how many identifiers were required to achieve the purposes. It was unclear within the application and it would be a matter of good practice to clearly define the data required to achieve the specific purpose. This approach would allow the activities which the PHOs carried out to be clearly defined, which would be beneficial to the future development of specific regulations to cover these activities.
6. Members recommended that there should be greater clarity over the internal governance arrangements within all PHOs, with a view to establishing a common standard across all observatories.
7. Members agreed that patient and public involvement was limited and that there appeared to be plenty of opportunities to strengthen this aspect and would expected the PHOs to do so before resubmission.

Action: NIGB Office to inform applicant of outcome.

4c. Commissioning Support for London (CSL) [ECC 7-04(c)/2010]

This application from Commissioning Support London was to allow access to identifiable HES data, including postcode, NHS Number and date of birth for both mother and baby in order to permit more detailed level analysis to support other services that CSL provided to their customers. A meeting with the applicant had taken place on the 27th September with a smaller group of members and this group fed back to the Committee at the meeting.

Members noted that they strongly supported commissioning activities. However members found the application to be unclear in terms of its purposes, and felt that these would benefit from being refined further. Members agreed that in order to provide section 251 support, a specific purpose for the use of identifiable data must be clear, as well as the overall aims of what is to be achieved. Members found this aspect difficult to assess, due to lack of clarity within the application.

Members discussed the information governance arrangements detailed within the application, and were not persuaded that the activity had sufficient information governance expertise supporting it. This aspect was of key importance to members. The Committee queried the specific arrangements over the internal process to manage governance, and discussed the internal approvals process for allowing access to patient identifiable data. Members agreed that these processes should be clear and well defined, and were not convinced that the arrangements within the application were as robust as they could have been.

Members queried how the data would be obtained from the GP practices, and were of the view that the transfer of this data should not take place without a secure legal basis being in place. The applicant informed members that this aspect had not yet taken place and members recommended that arrangements be made to ensure that any such transfer operates via consent from the patient or by notifying patients that the activity was to take place and providing an opportunity to opt out.

Members were clear that GPs could not provide consent on behalf of their patients, to transfer identifiable data.

The Committee also discussed whether this was a duplication of work that was already being carried out by the PHOs.

The Committee were unable to provide section 251 support to the application at this time and advised that any new application should clearly set out the purposes for which the data would be utilised, and the analyses to which they would relate. Further clarity was also requested over the intent of onward linkages, to whom these would be enclosed, and how management of inferential identification would be managed in publication.

Action: NIGB Office to inform applicant of outcome.

4d. Integrated Patient Care System "Stratify" [ECC 7-04(d)/2010]

This application from NHS Redbridge aimed to develop a predictive data processing system (known as Stratify) that allowed it to identify patients at risk of early admission to hospital from a number of illnesses. Stratify would take its data from a number of sources and locate it within one database. Section 251 support was required to access GP practice systems, secondary user services and community provider data to locate it within one centralised database.

Members considered this application in detail and were of the view that it outlined an innovative and potentially beneficial project. However there were some discrepancies within the application which made it difficult for members to thoroughly assess.

In particular, members found it difficult to distinguish between those activities that were deemed to be for the primary purpose of care and treatment of the patient by those who would have legitimate access to the patient's data, and those purposes which related to secondary uses. This was important as section 251 was not legally applicable to primary purposes of delivery of care. .

Members discussed that the application seemed to include some misunderstandings about the common law of confidentiality and noted in particular the reference to data provided to health professionals other than GPs not being covered by the common law duty of confidentiality. Members agreed that data provided to any health professional with a duty of care, if it originated from a consultation, or context of trust, would be confidential when used in an identifiable format.

Members noted the large amount of sensitive data to be collected and utilised. Members requested further details on the linkages involved, particularly over sensitive aspects such as mental health data, and noted that the application had not explicitly covered the possibility that GPs could receive additional data that would not be expected by the patient.

Members noted that the application was not clear why identifiable data was required for the secondary purposes and recommended that this should be explored in greater detail, as section 251 could only be provided where there was no other alternative. Members queried whether it was necessary to merge this data in order to get the outcomes proposed.

Members noted the intention to gain consent for the activity in the future, but that this would take place in 12 months time. They suggested that a written communication was made now to inform the population of the nature of the activity, and to provide them with the right of opt-out.

Members agreed that if suitably managed, this activity would be of significant benefit to its population. However as there was a lack of clarity over when the data was to be used for primary purposes of care and treatment, and for secondary uses, the Committee were unable to provide section 251 support.

Action: NIGB Office to inform applicant of outcome.

4e. Children's National Services Framework (NSF) Data Sets [ECC 7-04(e)/2010]

This application from the Department of Health would provide a source of data to support the planning of children's services in the future. The application proposed that throughout the mother's pregnancy and the child's life to age 19, data would flow from Trusts to a data warehousing facility to form a profile of the care events and associated demographic detail. The warehousing facility would pseudonymise patient data before it was stored in the reporting data warehouse, so that data users would not be able to identify individual patients. Section 251 was required for the flow of identifiable patient data to the data warehouse prior to data being pseudonymised.

Members agreed that the application was an important and essential development to provide an infrastructure from which to assess quality of health care and outcomes for children, young people and mothers. Members noted that it had been developed in consultation with a wide range of stakeholders including some public involvement members. Members were mindful that currently outcomes for a whole range of child health issues and services could not be assessed from a national level and that the benefits of bringing those together was undeniable. Members therefore agreed that the application provided a welcome integration whereby the information about a child would be linked to that of the biological mother and that this was vitally important for a wide range of public and clinical priorities.

Members were of the view that it would neither be feasible nor desirable for trusts to pseudonymise their data locally as the linkages would need to be carried out reliably across quite complex data sources. This would require some identifiers to be available and even if it could rely on NHS number it would still require a pseudonymisation or encryption approach to avoid disclosive risk via NHS number. This approach could be justifiable, only if the governance and disclosive risks were appropriately managed.

Members agreed that the application was not sufficiently comprehensive to allow support under section 251 to be provided. In particular they noted that there was a disparity between the attention given to specifying the datasets and the attention given to detailing the processing of the data.

Members discussed that the linkage methods and data flows within the interim warehouse, which would generate anonymised datasets from identifiable data, were not described. It was also noted that the application stated that technical staff would require access to identifiable data when dealing with quality and error issues. However, the Committee were not satisfied that they had been provided with enough relevant detail about this. The Committee advised that any resubmission would need to consider such access in sufficient detail.

Members noted that the draft dataset specifications provided by the applicant were confusing and appeared to contradict each other. Members felt that further clarification was required.

The datasets outlined within the application included sexually transmitted infections, mental health and aspects of social circumstance data. Members were clear that the Sexual Health Directions 2000 prohibit the use of identifiable sexually transmitted disease data for purposes other than direct care or preventing the spread of infection and therefore such data should not flow centrally in an identifiable format.

Members noted the directly and indirectly identifiable and sensitive data items and their handling, and welcomed the comment that these aspects would be kept under close review. However it was noted that the overarching governance arrangements for the three datasets were not clear and that these should be addressed in detail.

Additionally, members requested assurance over the handling of sensitive fields and management of the disclosive risks as this was not entirely clear within the documentation that was provided.

It was noted that the responses provided to the NIGB Office queries did not appear to answer the questions posed. Members were disappointed that the applicant had not engaged further with the office and advised that any resubmission should fully address the queries.

Members agreed that there should be strong and on-going commitment to public involvement. The Committee would welcome some comment on how discussions about the activity would involve patients in future. Information was requested on whether a separate and supported patient and public involvement group around the three datasets had been considered.

The Committee accepted that consent for this activity would not be feasible and therefore emphasised that they would not expect consent to be sought. Members requested that consideration be given to providing suitable fair processing information at a local level to allow patients to opt out of the use of their data if required.

The Committee could not approve the application, as it stood, but welcomed a resubmission taking into account the points raised.

Action: NIGB Office to notify applicant of Committee decision.

4f. Improving Access to Psychological Therapies (IAPT) Data Set [7-04(f)/2010]

This application from the Department of Health required section 251 to enable the monitoring of the newly established IAPT services in order to understand service provision and outcomes, and to inform service improvement. The cohort of the IAPT database would be those people accessing NHS commissioned IAPT services for depression and anxiety in England. Section 251 support was sought in order to provide a legal basis to enable the flow of identifiable patient data from IAPT service providers to Connecting for Health Systems and Service Delivery (SSD) prior to data being pseudonymised.

Section 251 support was required to provide a legal basis to permit the flow of identifiable data, patient demographics, observations, appointments, admissions and interventions from Trusts to the data warehouse (SSD) prior to data being pseudonymised.

Members agreed that this was important and that there was a public interest in this activity taking place. However when discussing the application, several concerns were raised about certain phrases within the application. Members agreed that the form did not provide sufficient justification of the extent of the identifiers to enable section 251 support to be provided.

Members noted that NHS number, postcode, local patient identifier and date of birth had been requested in order to create the unique patient ID number. It was noted that the dataset had gone through many revisions, but evidence was still inadequate. Some comments provided by the applicant were not considered to be specific enough, and it was felt that particular emphasis should be given to the justification for sensitive data items. Members queried whether the unique identifier could be created without the need for postcode.

Members discussed the reasons provided for not gaining consent. Members felt that as currently phrased, the application indicated that the patient entered the care environment a number of times, and therefore there were possibilities for consent to be obtained at the points of interaction. The application form described that services involved in patient care would provide information to patients about how patient data would be used. Members were unclear why these opportunities were not used to gain consent.

The Committee requested that the applicant revisit the responses they had given to the data protection principles, as they did not seem to demonstrate compliance with each principle within the context of the application arrangements. In particular, the fair processing requirement needed to be expanded, and definite clarification provided over the retention period. They also noted that the applicant should readdress user involvement carried out.

Members requested that a revised application form should be submitted to the NIGB Office and considered by fast track to determine if concerns had been addressed.

Action: NIGB Office to notify applicant of Committee decision.

4g. ECC 7-04(g)/ 2010 Tower Hamlets Bespoke Social Marketing Population Segmentation

This application set out the purpose of creating bespoke population segmentation, and aimed to provide patient identifiable data to a commercial third party in order to allow them to attach characteristics to the population within the PCT using bespoke software, and to link to a wide range of datasets and the summary characteristics. The purpose of this would be to allow the PCT to operate a wide range of functions including public health strategies, targeted public consultations and commissioning of services. It was noted that the application stated it was necessary to have a bespoke service due to the ethnic composition of the population. Section 251 was required for third party access to the Secondary Uses Services (SUS), mortality and birth data, GP and screening records in order to link with a pre-existing dataset held by Experian.

Members noted that the application requested access to a large amount of patient identifiable data. It was agreed that whilst there was public interest in the ability to characterise the population, a stronger case needed to be made for this, to justify the potential risks of using so much confidential data. Members felt there could be greater clarity over the purposes as it was not entirely clear how the activity would inform commissioning or help deliver improved healthcare; further information was needed.

The application set out reasons for the use patient identifiable data; these included the creation of bespoke social segmentation, to link datasets at individual level and to provide a comparison to the rest of England. Members queried whether the latter would be feasible as it was not clear who else would have this bespoke system. However, it was agreed that the first two purposes seemed valid. Members raised the point that there appeared to be some ambiguity over the intended purposes of the data when progressing through the application, and therefore they could not be clear on whether the number of identifiers requested were in fact necessary to achieve the purposes.

Members noted that GPs had provided consent on behalf of their patients, and were of the view it was not possible for GPs to provide this consent on behalf of their patients. Members could only identify limited information that had been provided about the data transfer/sharing agreements between the PCT and these various data providers. It was also noted that the GP consent form did not explicitly state that the data was going to a third party provider, so it was unclear to the Committee what had been consented to by the data controllers.

Members noted that the application stated that consent was not feasible and would result in bias. Members were unclear as to how the cohort would be informed, in advance, as to the nature of this activity, in accordance with the fair processing requirement of the Data Protection Act 1998,rather than after the data was processed. They requested that this be given further consideration.

Members discussed whether there would be a practicable alternative to the proposed disclosure. A proposal was raised to limit the extent of export of personal identifiable data for the segmentation, to develop the software so that it could be used by the PCT or data providers without the need for the data to ‘move outside’ of the NHS. An alternative approach would be to assign the social segmentation to the individual by linkage of health data in-house, using pseudonyms. In particular, members could not find a compelling justification why a third party was considered to be essential to carrying out the linkage, and why this could not be carried out in-house.

Members noted a statement made that the activity would allow people to be contacted only once for several issues, and were unclear as to whether part of this exercise would actually re-identify members of the public. They requested further information on this point.

In reviewing the documentation, members felt there to be a lack of clarity about the third party's organisational perspective on personal data, the permissions needed and legal status of the data flows. Members noted that it was argued that the data was not personal and that postcodes would only identify households and not individuals. Where a household had only a single resident the application stated that 'exclusion controls' would be put in place, however these were unspecified. Members agreed that postcodes and households were disclosive in combination with other data even where there was more than one individual per household.

Members noted the suggestion within the application that the third party were only processing the data and that no legal transfer of data would take place, even though it appeared that they would enter into an agreement with the data controller to provide 'legal safeguards'. Members felt there to be some confusion in this statement.

Members noted that a pseudonymised code for the identifiers was to be used, but insufficient detail was provided to permit the Committee to identify whether this was appropriate. Generally, members felt that more detail should be provided over the precise methods of data linkages. Members discussed whether in this case those processing personal data would have a duty of confidentiality equivalent to that of a healthcare professional, and agreed that further information would be required to determine whether this had been established.

Members were unable to provide section 251 support to the application in its current form. This was on the basis of the above discussion and that further justification would be required to demonstrate why the same assignment of social segmentation could not be established using a more limited set of information which could be pseudonymised and returned to data custodian for linkage.

Additionally, members recognised that it was likely that there would be significant increase in the number of applications from commercial organisations, and were of the view that they should demonstrate equivalent standards to those applicable to the NHS.

Action: NIGB Office to notify applicant of Committee decision.

4h. ECC 2-06(a)/2009 – Small Area Health Statistics Unit (SAHSU) Health Database – extension request

This application was for a request for an extension to the original SAHSU application (ECC 2-06(a)/2009), which requested an additional dataset, Myocardial Ischemia National Audit Project (MINAP); to extend the holding of NHS Number and date of birth, and to carry out further cross-linkages across datasets.

Members noted that there was a strong public interest in the purposes of the application. They also noted that a considerable amount of work had gone into producing the application and that it was very detailed.

However, unfortunately the Committee found that due to the level of technical detail there was some difficulty in identifying the core issues. For example, whilst members appreciated the comprehensive summary of the purpose of the application, they found it difficult to establish the precise rationale for the requested extensions within this section. It appeared that more identifiers had been requested than were actually required and further clarification was requested.

Members discussed what was meant by "unrestricted cross linkages" as the phrasing implied a wide range of linkages and were not sure as to what this entailed in practice.

Members noted a local Research Ethics Committee letter that provided a general favourable opinion of research studies to be carried out by the applicant. However they queried why the letter did not come from an NRES REC and requested clarification, as some of the data being accessed was health data and should therefore be reviewed under the criteria set down in the NHS Research Governance Framework.

Members agreed that they did not have sufficient clarity to allow them to approve this application. However as they were keen to support this activity, they requested a letter to address the concerns raised and provide clarification. This letter could then be considered outside the Committee by a group of members.

Members advised that the letter should provide:

1. Clarification over what additional identifiers were requested, and justification for each item. Consideration should be given to reducing the identifiability of data, such as date of birth to age bands.
2. Clarification should be provided over the phrase “unrestricted cross linkages” and the scope of this identified
3. Rationale should be provided as to why a review by a NRES REC was not appropriate for the research arm of the application.

Action: NIGB Office to notify applicant of Committee decision.

4i. ECC 7-04 (i)/2010 Blood Stream Infections: Focus on Outcomes

This application from North Bristol NHS Trust detailed a study that aimed to identify risk factors associated with all causes of death in patient with blood stream infections involving specific pathogens. Additionally it hoped to discover risk factors leading to death or prolonged stay in hospital from the blood stream infection alone and the timelines of these risk factors to see if modification could be made to the patient pathway to improve outcomes. Section 251 support was required to allow a researcher access to hospital administration systems, laboratory systems and medical notes within five centres, and also to permit the collection of mortality data.

Members agreed that there was a clear public interest and strong patient benefit to this activity taking place. Members discussed the reasons given for not seeking consent. In particular members noted the view that many patients would not be asked for consent because their doctor judged that seeking consent for the use of personal data would be too burdensome at the time of diagnosis.. Members did not consider this reason itself to be persuasive without further evidence as section 251 support could not be used to suit administrative convenience. .

Members discussed the second reason cited for not gaining consent, which was the bias and impact of scientific validity of the study, nature of patient illness and size of the cohort. Members also took into account the previous pilot study that had taken place and thought that this added great weight to the arguments given.

Members noted that the applicant had carried out a good amount of patient engagement in developing this study and the Committee welcomed this positive step. It was also noted that a limited amount of patient identifiable data had been requested to carry out linkages: namely NHS number, Hospital ID and name.
Members agreed to approve this application subject to the revision of the data protection principle question.

Action: NIGB Office to notify applicant of Committee decision.

4j. ECC 7-04 (j)/2010 - Long term risks of paediatric fluoroscopic cardiology

This application from Newcastle University was to establish a registry for long term follow up of children and young adults who underwent fluoroscopic cardiology procedures and assess their cancer risk in relation to the estimated radiation doses they received. Section 251 was required to allow the flagging of the cohort on the central register and patients to be matched with congenital anomaly registers to identify the heart defects involved and infants with Down's syndrome. Exposed individuals would be identified primarily from records of radiology and paediatric cardiology departments in Great Britain where interventional cardiology is performed in paediatric patients. The application required access to name, date of birth, hospital ID, NHS number, postcode, address and sex for linkage purposes.

Members noted the view that it would not be feasible to obtain consent from the 15,000 previously exposed subjects and that it would not be ethical to do so since it might raise doubts in their minds which could not be addressed without further information. Members agreed that this was a reasonable assertion and concurred with the evidence that consent would not be possible.

Members noted that there was no patient and public engagement strategy detailed within the application and were of the view that this should be pursued. Members agreed that the consultation with a radiology patient liaison group could be improved upon, and advised that there was an established patient group of children with heart defects (Heartline) who could be approached to discuss the activity.

Members recognised the importance of this study; however they agreed that they would need further detail about the nature of the cohort. Members were unsure whether the entire cohort would be retrospective, and advised that consent should be explored for any prospective arm of the cohort. Members were also concerned that there would be no reference population of unexposed fluoroscopy patients.

Members noted the statement that the patient identifiable data would be retained without consent for a period of fifteen years. Members felt this to be excessive in terms of compliance with the Data Protection Act principle to retain data only for as long as necessary and that steps ought to be taken to reduce the identifiabilty. Members therefore requested further justification for the retention of this data.

Members agreed to provide provisional approval to this application subject to satisfactory responses to requests for clarification:

1. Clarification regarding the lack of reference population.
2. Applicant to provide a rationale for the retention period of fifteen years and consideration to be given about what steps could be taken to reduce the identifiability over time.
3. Clarification over whether consent could be obtained prospectively; applicant to give consideration to the feasibility of carrying out this approach on a pilot basis.

Once satisfactory clarification had been received this application could be approved subject to the following conditions:

1. Patient engagement to be carried out with an appropriate patient group such as Heartline and feedback from this engagement to be provided to the NIGB Office in the annual review.

Action: NIGB Office to notify applicant of Committee decision.

4k. ECC 7-04(k)/2010 Fenland Study – A population based cohort study of the interaction between genetic and lifestyle environmental factors in determining obesity, type 2 diabetes, insulin sensitivity, hyperglycaemia and related metabolic disorders

The Fenland Study commenced in 2004 and was a population-based cohort study investigating the interaction between genetic and lifestyle environmental factors in determining obesity, insulin

sensitivity, hyperglycaemia and related metabolic disorders. Participants were recruited via GP surgeries in Cambridgeshire and the application sought support under section 251 to enable the researcher team to continue to transfer minimal contact details of those eligible from the GP surgery and invite them prior to gaining consent. In addition, to demonstrate population representativeness, the application also sought approval to hold non-identifiable information about the population who did not consent to being studied.

Members agreed that this was a clear application and a well-designed study, and they were supportive as it provided a clear public benefit.

Members noted that the intention was to scan the GP's signature onto letters to be sent to patients, and the Committee were of the view that the GPs should be made aware of whom the information had been sent to as a matter of good practice.

Members discussed the applicants request to hold non-identifiable information about those who choose to withhold consent. Members requested further clarification on what this data would consist of. Members also queried whether the cohort could be informed that they might receive further information as the researcher would no longer hold patient identifiable information.

Members noted that a volunteer would assist the GP in carrying out the exclusions for the initial recruitment and requested clarification over the assistance that would be provided and the extent to which this would permit access to identifiable data

Members agreed to provisionally approve this application subject to satisfactory clarification of the following:

1. Confirmation of what data items would be held about those who chose not to consent.
2. Whether the cohort could be informed that they might receive further information if they did not consent as the researcher would hold no identifiable information.
3. Clarification on the role of the volunteer and their access to patient information.

Action: NIGB Office to inform applicant of Committee decision.

4l. ECC 7-04(l)/2010 Factors associated with recurrence and length of survival following relapse in patients with neuroblastoma: a pilot study

This application from the University of Newcastle set out the purpose of investigating factors associated with recurrence and length of survival following relapse in patients with neuroblastoma, by combining epidemiological data, clinical and biological data. Section 251 was required in order to permit a researcher access to data held by three cancer registries so as to extract relevant data and to populate a new database.

Members noted that this was a relatively small study that would take place over three sites where 140 were expected, with a total cohort size of 352. Members agreed that this application involved a rare condition and therefore it was important for this work to take place. Whilst mindful of its importance, Members did raise questions about the establishment of an additional database and were of the view that this should be minimised and existing data sources utilised wherever feasible. This point was made particularly in relation to the cancer registries who could collate the identifiable data and therefore the researcher could be provided with a de-identified dataset.

Members were mindful that support under section 251 could only be provided where there was strong justification that there was no other reasonably practicable method to either seek consent, or receive pseudonymised data. Members accepted that it would not be possible to obtain consent

from the deceased for obvious reasons; however members queried whether de-identified data could be obtained in relation to the deceased.

Members were also of the view that the few of the cohort who would be alive could reasonably be approached via their oncologists. Members also queried whether the consultants could collate the relevant patient information for patients who were alive and anonymise it before it would be released to researchers.

The Committee was of the view that utilisation of de-identified data would achieve the purposes of the activity. They were therefore unable to provide section 251 support to this application. It was recognised that there might be an issue in obtaining de-identified data for deceased persons and the Committee advised that if this was the case an application for this data could considered via fast track procedure.

Action: NIGB Office to notify applicant of Committee decision.

5a. Conflict of Interest policy ECC 7-05 (a)/2010

Members were provided with the NIGB policy on dealing with conflict of interests.

Denis Pereira Gray expressed his disappointment that the policy did not insist that those with a conflict of interest leave the room on every occasion so as not to take part in discussion.

Agreed:

1. **The Office would seek to minimise conflicts of interest when allocating applications.**
2. **Members would notify the office if a conflict of interest was known in advance.**
3. **The Committee would clearly register conflicts of interest at start of meeting and the Chair, mindful of members views, would take appropriate action.**

6. Any other business

No further business was discussed.

7. Future meeting dates

- 1 December 2010
- 3 February 2011
- 29 March 2011