Meeting held on Thursday 21st May

Present

Members: Professor Dame Joan Higgins (Chair), Mrs Pauline Brown, Dr Tony Calland, Dr Patrick Coyle, Dr Fiona Douglas, Ms Stephanie Ellis, Mr Michael Hake, Ms Ros Levenson, Professor Roy McClelland, Ms Sue Parroy, Dr Mark Taylor, Mr Terence Wiseman.

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

1. Welcome and apologies for absence

Apologies for absence were received from Professor Mike Catchpole, Dr Tricia Cresswell, Professor Carol Dezateux and Professor Sir Denis Pereira Gray

The Chair welcomed two new Members to the Ethics and Confidentiality Committee (ECC); Dr Tony Calland, a retired general practitioner and the Chair of the BMA Ethics Committee, and Professor Carol Dezateux, a paediatrician and Director of the MRC Centre of Epidemiology for Child Health at the UCL Institute of Child Health. Both new appointees are representative members of the National Information Governance Board (NIGB).

The Chair welcomed Ms Parkinson, NIGB Officer, as an observer to the meeting, and Ms Edgeworth, NIGB Business Support Officer, who had been recently appointed to the NIGB Office and would be preparing the minutes.

2. Minutes of last meeting

1. Minutes of the last meeting held on 25 March [ECC 2-02/2009] were approved, subject to minor amendments.

2. The Chair provided an update on Item 5 of the previous minutes and informed the Committee that a meeting had taken place with the NHS Information Centre (NHS IC), to discuss the NCASP application and to set out the requirements of the Committee for the review at the July ECC. The meeting was chaired by Professor Pereira Gray and attended by representatives from the NHS IC, the NIGB Office and some ECC Members. Members noted that this had been a useful and constructive meeting. Members were reminded that the NCASP application would be heard at the July meeting in line with its 4-month review cycle in order to determine whether approval would continue to be provided.

3. The Chair provided an update on the Department of Health Attribution Data Set application [ECC 2-06 (h)/2009] and noted that the security arrangements had been assessed by the independent security adviser. The adviser reflected the concerns of the Committee and had not found the arrangements to be satisfactory, therefore neither the ADS nor GP Market Share Analysis [ECC 2-06 (i)/2009] applications could be approved as they both utilised the same working arrangements of the contractor.

Correspondence from the Department for Health to the NIGB Office indicated that they would seek to investigate appropriate home working arrangements, or to bring the contractor under the organisational security arrangements.

4. Item 7.2 of the March minutes indicated that a Deputy Chair would need to be appointed. A nomination and voting process had been carried out and the Committee agreed that Professor Pereira Gray would be Deputy Chair of the Ethics and Confidentiality Committee.

3. Matters arising/action points

3.1 Secretariat Report [ECC 3-03 (a)/2009]

1. Dissenting from disclosure for research purposes

The NIGB Office had received an enquiry from an individual wishing to dissent from disclosure of their personal data for research purposes, including under Section 251. The individual had been informed that the only way to currently achieve this was to contact all of the organisations from whom the patient had received care to ask that their records be marked as dissenting from research. The Information Governance Lead had advised that there was no single route for dissent and that it was unlikely that data that had already been disclosed for research purposes could be withdrawn.

The individual was dissatisfied with this approach and felt that there should be a simple and single route to dissent from research. The Information Governance Lead followed this up with NHS Connecting for Health (CfH) to ascertain whether there was a national flag or plans for a flag to facilitate such dissent. It was identified that there had been a flag planned for the Personal Demographic Service for dissent from secondary uses of data but that this had been withdrawn in 2004. This was, to some extent, understandable, as 'secondary uses' was too broad a term to be useful.

The issue of dissent had been raised with the NHS CFH Information Governance Team, the Research Capability Programme and with Digital Health Information Policy for their consideration. Phil Walker agreed to take ownership of this issue in policy terms. The enquirer also raised this as an issue in relation to Section 251 approvals, therefore the Committee were asked to consider whether there might be a means of facilitating dissent specifically in relation to Section 251 approvals.

Members were sympathetic to the issue and recognised the importance of a mechanism to allow dissent in relation to section 251 approvals of secondary uses of data. Members also noted that section 251 support should not be used to override individual dissent and that it was a permissive rather than mandatory power. Members debated whether this issue was within the remit of the Committee's control as it approved applications for cohorts rather than individual patients, and did not hold any patient identifiable information relating to applications, Members discussed whether it would be reasonable for the Committee to hold a list of patients who wished to dissent from inclusion within section 251 approvals. However, it was agreed that as the Committee did not hold any identifiable data on patients that this Register would not be practicable as the Committee would not be able to link the details on the Register to any specific cohort being studied. Following discussion, it was agreed that it was neither feasible nor appropriate for the Committee to handle individual instances of dissent and this must be dealt with by the applying researcher. It was agreed that researchers making a section 251 application should explicitly address how they would allow people to dissent from the research and that the application form should be amended to include this.

An additional point was made that this concern raised an important issue over dissent and the feasibility of a simple mechanism to facilitate this on a national basis. Dr Calland agreed to discuss the issue with the NIGB.

Action: **NIGB IG Lead to feedback discussion to enquirer**

Action: **NIGB Office to ensure question of dissent is explicitly addressed by future applicants**

Action: **NIGB views to be sought on issues around dissent**

2. Relationship with Human Fertilisation and Embryology Authority (HFEA)

Following the passage of the Human Fertilisation and Embryology Act in 2008, which would come into force on 1 October 2009, it was reported that the NIGB Office has been in discussion with the HFEA on provisions allowing confidential patient information relating to fertility treatment to be disclosed to researchers. The Act established powers, similar to Section 251, for the HFEA to approve disclosure of HFE data to researchers. Separate powers would be created to cover both medical and non-medical research and HFE data in all four home countries.

As a result of these discussions, there was agreement, in principle, that the Ethics and Confidentiality Committee would consider applications for patient identifiable HFE data for medical purposes. Through delegated powers from the HFEA under Section 25 of the HFE Act 2008[1], the ECC would be able to approve disclosure of HFE data for Scotland and Northern Ireland. Applications which sought to link to non-HFEA data in Scotland and Northern Ireland would need to seek separate approval for the linked data from the relevant body in the other country. The HFEA would establish its own process for disclosure of HFE data for non-medical research.

The Committee were notified that discussions were still ongoing in relation to consent issues.

3. ECC guidance update

Members were informed that the NIGB office had commenced work on updating ECC guidance. The initial stage would be to ensure that all documents and guidance currently available correctly referenced the London address, contact details and changes reflecting the NIGB. The longer term plan would involve developing the website to be more user friendly, and to develop some frequently asked questions and scenarios which would make clear when there is a need to apply.

In addition to this, the NIGB Office had been in contact with the IT team regarding development of a new register/ applications management tool. This would incorporate s251, HES and MRIS applications, and would be intended to be a tool where applicants could upload information themselves for their annual review and other purposes. This should ensure a smoother administration of the application process. This would involve integration with IRAS therefore initial discussions would shortly take place to progress this.

[1] Section 25 creates a new section - 33D in the 1990 HFE Act.

4. IRAS update

The NIGB Office recently attended the IRAS Management and Project Board meetings. In order to monitor the uptake of the use of IRAS in moving towards it being the preferred mechanism for research approvals, a request had been made for a report to be provided on the percentage of applications received via IRAS for the June period. The NIGB Office informed the Committee that they currently collated this information as a matter of course.

The recent set of applications had demonstrated that there are a number of concerns raised by applicants around fields that have not been populating correctly. The Office is in the process of collating these issues with a view to bringing these to IRAS for discussion and resolution.

5. Extensions granted to existing approvals

PIAG 3-04(b)/2006 (MR1062):

This was a retrospective case-control study of melanoma patients who had undergone sentinel lymph node biopsy. The extension request was to include cancer and death notifications from the Central Register.

PIAG 1-05(b)/2008:

An application from the NHS Information Centre sought to extend the previous Hospital Episodes Statistics approval by 12 months. This was approved.

6. Applications considered under the fast track process

ECC 2-06(FT1)/2009:

This application set out an audit and evaluation of the impact of the introduction of the NICE guideline 50 for acutely ill patients at North Tees and Hartlepool NHS Trust. Section 251 support was required to access the notes in order to extract pseudonymised information.

The application was reviewed by the Chair and two Members, Ros Levenson & Mark Taylor, and approved.

3.2 ECC Administrative Review update [ECC3-03(b)/2009]

The NIGB Business Manager presented the findings of the recent administrative review of the processes around the handling of applications to the Committee and DMsG. The review had been carried out by an independent consultant and the primary focus had been to assess whether the application process was fit for purpose in terms of being responsive and transparent to stakeholders, that relevant information was properly recorded so that it could be performance managed. It was emphasised that the review was not intended to be a critique of the process in the past and that due to the changes to the ECC and staffing, it had seemed timely to conduct the review at this point.

The key message had been that as a whole, the process was deemed fit for purpose. Recommended improvements included development of an applications database and a project to improve the website and guidance had been initiated.

In order to minimise the small number of instances where an application had been resubmitted, the Committee were asked to consider what would be the minimum set of documents required for an application to be fully considered by the Committee. Members noted that a checklist of the minimum set of required documents was contained within IRAS and the guidance on the NIGB website. It was also noted that the nature of the application would determine the nature of the additional documents required. It was agreed that some generic mandatory documents, such as confidentiality policies, did not need to be viewed by the Committee provided that the NIGB Office had assured themselves that the documents were suitable.

Action: Summary sheet to be amended to reflect those documents received and checked by the NIGB Office

It was also agreed that a full set of mandatory documents must be received by the NIGB Office prior to submission deadline otherwise the application could not proceed to a Committee meeting. This would bring the process in line with Research Ethics Committees. It was also noted that the finalised version of documents should be submitted rather than draft documents; if not feasible then on an exceptional basis the applicant would need to provide reasonable justification to explain why final versions had not been submitted. Members agreed that as a whole they would not accept draft applications and that in these instances, the applicant should work with the NIGB Office to prepare a full and complete application to the defined submission deadlines. However, the Committee agreed that they would consider instances where a general view on a topic would be required from the Committee and they would respond to questions around an application, provided that the queries were specific. It was noted that there was a section on IRAS where applications had the opportunity to provide any further information they would like the Committee to consider and that applicants should be encouraged to complete this.

Action: Final versions of application and set of mandatory documents to be received by the NIGB Office prior to deadline submission otherwise application would not proceed to Committee meeting

The Committee confirmed that they should consider patient information leaflets in order to give an opinion where appropriate, however it was noted that if significant changes to leaflets were requested this would require an amended version to be submitted to the REC.

Members noted that some MRIS applications to the Database Monitoring sub Group (DMsG) require S251 support. In order to ensure that all s251 applications would be handled consistently in line with NIGB delegated powers, Members were asked to approve the change for MRIS applications that required s251 support to be considered by the Ethics and Confidentiality Committee rather than the DMsG. Members agreed to this proposal and it was agreed that the NIGB Office would carry out the necessary arrangements with the NHS IC so that MRIS applications requiring section 251 support would be considered by the ECC from the July meeting.

Action: MRIS applications requiring s251 to be submitted to the ECC, from July 09

3.3 Chair's report [ECC 3-03(c)/2009]

1. New Members of the ECC

The Chair provided a summary of the independent appointments process following a request from the NIGB for two Members of the Board to be appointed to the Committee. The Chair provided a summary of the expertise of the new members, Dr Calland and Professor Dezateux, and that the Committee would benefit from their considerable experience and knowledge.

2. Meeting with the NHS Information Centre (NHS IC)

A number of ECC Members, together with NIGB Office staff, met colleagues from the NHS IC and the Research Capability Programme on 27 April. The purpose of the meeting had been to provide an informal view on an early draft of the NHS IC's proposals for S251 Specific Support and changes to Regulations. It was an opportunity to provide feedback on the draft and to indicate how the ECC would potentially respond to their proposals. Attending Members agreed that the application would need to separate out the various activities as a broad approach would not be appropriate.

3. National Information Governance Board (NIGB) meeting

A meeting of the NIGB was held on 15 April 2009 and the Chair provided an update on the issues discussed.

The NIGB had received a report from the Disputes Resolution Working Group (DRWG), which had been looking at how and whether changes should be made to patient records in cases where there was a dispute. The report reinforced the current view that changes should be made only in the most exceptional circumstances, and then only to add information and not to remove information from the record. This was an important principle not just for clinical reasons but also in cases where litigation could arise. The report would be issued for public consultation for three months.

Action: DRWG report to be made available to Committee Members

One of the NIGB Working Groups received an update from the GP Extraction Service (GPES), which had been making good progress, under the aegis of the NHS IC, in developing a service, which would initially be for the NHS but which might become available to researchers in the future. The GPES would be developing clear protocols that emphasised that applications for access to identifiable data would need to come to the Ethics and Confidentiality Committee for section 251 support. At this stage it was not clear what level of demand there would be for the new service, but it could have implications for the workload of the Committee. The Chair noted that GPES had made significant efforts to be a model of good practice and they had received encouragement from the NIGB in progressing this.

The NIGB approved the ECC Complaints and Appeal process, with minor modifications, and it had been published on the NIGB website.

The Board commented on a revised version of the Care Record Guarantee and discussed the launch of the Social Care Record Guarantee that would be implemented by each local authority.

4. DMsG Report [ECC 3-04/2009]

The DMSG Chair presented a written report on the status of applications and approvals. The DMsG Chair also discussed the issue of HES sensitive data items. The Committee had asked DMsG to review these data items and due to a number of issues, it was acknowledged that

this had taken longer than anticipated. The area that still required resolution was data items related to mental health. The point was noted that making mental health data items more sensitive could potentially stigmatise mental health, and it had been suggested that it would be helpful to consult with the relevant patient groups. The NHS IC had agreed to carry out a small consultation to help inform this.

It was agreed that due to the understandable delay over the mental health data items, that a paper would be presented to the Committee, minus these items, for the July meeting.

Action: HES sensitive items paper to be presented to ECC in July meeting

5. Applications previously considered

i. HES and STATS19 one to one matching project[PIAG 1-05(g)/2007]

This application was a resubmission by the Department for Transport regarding one to one matching of HES and STATS19 data in order to obtain a detailed analysis of the link between circumstances of road traffic accidents and the resulting injuries. The Committee noted that this application was previously approved by the Patient Information Advisory Group for access to patient postcodes from HES. This application was an extension of the previous approval in order to update the data. This research had a dual purpose as it would also provide estimates of under reporting and misclassification of road casualty data. Section 251 support was requested so that patient identifiable data from HES was available for successful matching with data held by STATS19.

The Committee were satisfied that the applicant had taken reasonable steps to address previous conditions imposed by PIAG and was pleased to note the involvement of Headway. However further user involvement from relevant patient organisations, was recommended.

This application was discussed extensively by the Committee and Members agreed that it had a legitimate aim and the purpose was focused around a difficult problem that would be of benefit to the public. The Committee noted that the application had previously been borderline in terms of falling within medical purposes and although supportive of this study, the question was raised over whether the purpose of the application could be classed as a medical purpose, as defined in the Health Service (Control of Patient Information) Regulations 2002. Members considered that the wording of the application proposed that the study dealt more with the prevention of accidents rather than patient care, although there was an implicit link to patient care. Members agreed that the purpose was much clearer than that stated in the previous application; however there were extensive deliberations over whether the purposes were sufficiently defined to fall within the classes of support provided within the Control of Patient Information Regulations, or whether it could fall within the public health regulations due to its investigations into environmental hazards. On balance, Members were persuaded the purpose of the application would inform the management of the health service, care and treatment and therefore it would fall within medical purposes.

It was agreed that the applicant should seek to obtain NHS sponsorship via the Department for Health, and the NIGB Office informed the Committee that this issue had been raised with the applicant prior to submission and the applicant stated their intention to progress this.

Members agreed that it would be of benefit to explore further the definition of medical purposes and requested that this be placed on a future away day agenda.

Members additionally questioned whether in future it would be appropriate and possible for the NHS IC to carry out the linkage of data.

The Committee approved this application subject to the following conditions:

1. Aspects of the application, specifically that of the stated purposes, should be redrafted to explicitly fit within the medical purposes and class support as defined within the Regulations stated above.

2. Further user involvement should continue and be reported in the annual review

3. The Committee considered that in the future it could be possible for the NHS Information Centre (NHS IC) to carry out the linkage, and this option should be explored and details provided in the annual review in moving towards this position

4. Diagnostic Codes have been requested, and it should be ensured that, in order that the amount of data obtained is not excessive, that the clinical data be limited to factors solely relevant to road casualty injuries

5. The possibility of obtaining an NHS sponsor, specifically that of the Department of Health, should be investigated and progress reported to the NIGB Office, and stated in the annual review.

Action: NIGB Office to notify applicant of Committee decision.
Action: Interpretation of medical purposes to go on away day agenda.

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

This application was a resubmission from the University of Leeds following a request from the Committee in its March meeting. The application covered plans for a research database of data on children who have been diagnosed with a life limiting or life threatening conditions, aiming to improve prevalence data on children and young people with these conditions. Section 251 support was requested for collection of patient identifiable data in order to check that each child was only registered once. At the March meeting, the Committee had agreed that there was no clear research hypothesis, that it appeared to centre on service planning and that if considered research that a resubmission should be made. Members had agreed that due to the small numbers involved, the level of patient contact and beneficial nature of the database, the cohort population would be likely to cooperate, therefore the resubmission should fully explore these options and provide detailed evidence as to why consent could not be sought, and detail appropriate user involvement.

The Committee assessed this resubmitted application against the points made from the March meeting. The Committee agreed that the applicant had not appropriately addressed the issues of consent raised from the previous meeting. . Members were not persuaded by the point that as some of the cohort would be terminally ill it would cause distress to be approached for consent. A view was raised that this was a paternalistic approach and in such situations, it would be less intrusive for the clinician responsible for the care to make approaches for consent, rather than an external researcher. Members noted that there might be difficulties in obtaining consent from some of the sub-cohort as they would be cared for by a disparate group of clinicians, however, section 251 support could not be used to overcome this without further evidence.

Patient involvement was a concern for the Committee and it was felt that insufficient attention had been provided in this area. At present the approach described in the application was deemed insufficient.

The Members decided that there was still ambiguity about how the data, once collected, would be used. They noted the establishment of an advisory board, however this was not considered sufficient in terms of gaining approval for section 251 support. Concerns were raised that at present there was no way of auditing the accuracy or completeness of the proposed database.

Whilst sympathetic to the overall purpose of the application, as detailed reasons and evidence had not been provided to the Committee in response to the issues raised in the previous request for resubmission, the Committee were unable to approve this application.

Action: NIGB Office to notify applicant of Committee decision.

6. New Applications for Section 251 Support

i. Traumatic Coagulopathy and Massive Transfusion: Improving Outcomes and Saving Blood [ECC 3-06(a)/2009]

This application was from the National Blood Transfusion & Transport Service to extend a previous application to obtain HES mortality data to enable linkage with anonymised TARN data. Support from section 251 was requested because of plans to link patient identifiable information obtained from more than one source to validate the completeness and quality of the information.

Members agreed that consent would not be feasible due to the nature of the trauma experienced by the cohort, however Members queried why retrospective consent could not be sought in some instances.

Discussion regarding the data flow which was proposed for this study concluded that the need for researchers to have access to identifiable information could be avoided. Patient identifiable data was required for linkage but it was considered that this could be successfully completed by the local TARN coordinator, who could then send it on the NHS IC. If this could be done then it would negate the need for section 251 support.

Members were not satisfied with current plans for informing patients. They agreed that if section 251 support was given then patient information would need to be improved to inform and advise patients of the study and to allow dissent.

The Committee were generally happy to provisionally approve the study; however, they requested a response to the following query prior to taking a final decision. If a satisfactory response was obtained, then a final decision could be taken by Chair's action outside of the Committee's normal meeting schedule.

The Committee requested further clarification before a decision could be reached:

1. The Committee understood that the local coordinator collected patient identifiable information which would be sent in anonymised format to TARN. TARN could then link the de-identified data with data held by the NHS Information Centre (NHS IC). Members queried why the local coordinator could not send the information directly to the NHS IC.

If the Chair was satisfied by the response to the above request for clarification, any final approval given would be subject to the following condition of approval:

1. Patient information leaflet should be included within the study to allow for patient right of dissent

Action: NIGB Office to notify applicant of Committee decision.

ii. The Bristol Self-Harm Monitoring System [ECC 3-06(b)/2009]

This application came from the University of Bristol with the purpose to set up a database/register of all hospital attendance due to self-harm to monitor rates and patterns and monitor current practices against NICE standards. The database would facilitate audit by providing data on the current management of patients for evaluation by clinicians and managers against standards set out in NICE guidelines for the management and treatment of self-harm. Section 251 support was requested in order to access demographic, psychiatric and clinical data to establish the database.

Members discussed this application at length and noted that it appeared to be predominantly audit, particularly as the activity would be carried out in a single hospital and the custodian would be part of the clinical care team of the cohort. Additionally, as it would be carried out within the care pathway it would be reasonable to assume implied consent for the use of this data for local audit purposes. As such, it was agreed that section 251 support would not be needed for this purpose.

In terms of user involvement, Members noted that the Samaritans had been involved, however, the application did not state the scope of their involvement or how their input had impacted on the study. Members felt that considering the extent of patient identifiable information requested, greater user involvement would have been expected. Most importantly, the application did not address, in detail, the issue of consent and any difficulties that would be involved in trying to obtain this from the cohort. Due to the small cohort involved, the Committee felt that obtaining consent would be feasible.

As a whole the Committee, due to the reasons above, considered the activity to be audit and commended the purpose of carrying it out in terms of good practice. As such, section 251 support would not be required to carry out this local audit. However, if the data was intended for research purposes, it was agreed that as the cohort was relatively small either pseudonymised data should be used, or consent should be obtained.

Action: NIGB Office to notify applicant of Committee decision.

iii. Preventable Incidents, Survival and Mortality Study (PRISM) ECC 3-06(c)/2009

A request for section 251 support came from the London School of Hygiene and Tropical Medicine in order to allow access to HES-ONS linked data and full medical records of patients who died upon admission or within 30 days following discharge. Access to HES-ONS data and medical records was required to create a randomised review of incidents where these circumstances occurred and to identify adverse events and contributory factors.

Members agreed that this was a worthwhile study and that it would be important to understand what had led to these outcomes. It was also agreed that the application had justified the methodology and why consent /pseudonymisation was not feasible in this instance.

The Committee was concerned that the application was unclear about what the information arising out of the research would be used for and was also ambiguous regarding the methods of disseminating the information. The role of a national newspaper health editor as a collaborator was another issue and one the Committee felt that it needed clarification.

The Committee strongly supported the purpose and provisionally approved the application, subject to the request for clarification concerning the following points:

1. The applicant was to specify the role of Mr Jeremy Laurence within the study; whether his involvement was confined solely to that of communication and confirm that he would have no access to patient identifiable information.

2. Clarification about why ethnicity as an identifier would be required.

Action: NIGB Office to notify applicant of Committee decision.

iv. Persistent scar problems following caesarean section ECC 3-06(d)/2009

This application from the Southend University Hospital NHS Foundation Trust proposed a study exploring healthcare experiences of women with persistent post-caesarean scar problems, including incidence and impact, in order to recommend changes. Section 251 support was required in order to access patient information to identify a cohort group to be sent questionnaires and seek consent.

The Committee discussed that the detection of this problem was based solely around information found on the internet in “blogging” sites; it did not appear that this subject was seen as a problem by health professionals. The Committee questioned why the researcher could not attempt to interview health professionals first to establish whether or not this was a legitimate problem.

The Committee also noted an anomaly in the Research Ethics Committee approval of this study; this application had been approved by the REC on the condition that the applicant obtained section 251 support. In line with the Health Service (Control of Patient Information) Regulations 2002, any section 251 support is restricted to that approved by the relevant Ethics Committee.

Concern was also raised over the proposed methodology for this study. After considerable discussion the Members agreed that due to the relatively small cohort stronger justification was necessary to explain why access to the cohort’s contact details should be provided to a researcher outside of the clinical care team. The Committee agreed that the first approach should be made by a treating clinician and not a researcher, therefore negating the need for section 251 support.

The Committee concluded that the clinician(s) directly responsible for the care of the cohort should identify and obtain the contact details of the cohort, without disclosing these details to the researcher. The researcher should prepare all of the necessary questionnaire information in sealed envelopes and transfer this to the treating clinical team, who would then label and send these envelopes on behalf of the researcher. If carried out in this way, there would be no disclosure of patient identifiable information outside of the clinical care team, and consenting patients would return the questionnaire directly to the researcher.

Action: NIGB Office to inform applicant of Committee decision.

v. West Yorkshire Cardiac Magnetic Resonance Research Database ECC 3-06(e)/2009

This application was from Leeds Teaching Hospital NHS Trust for an investigation of long-term outcomes in term of morbidity and mortality on cardiac patients. Support under section 251 was requested to obtain patient details in order to seek consent.

The Committee considered this application at length and concluded that this was a worthwhile study. However, this application was for both retrospective and prospective data. It was not immediately clear whether the application sought section 251 approval for both sets of data. Whilst Members appreciated that consent may be hard to obtain for retrospective data, section 251 support could not be provided for prospective data as consent was considered achievable. Members felt that when approaching the cohort for consent for prospective data it would be most appropriate for the GP or hospital providing care to make the initial approach.

The Committee were not persuaded that the application fully addressed the issue of user involvement and Members considered that they would wish to see more user involvement within this study, and how the views expressed in this involvement has impacted the development and methodology of the study.

Some sections of the application form were noted as needing further explanation. Members were not persuaded that the application had addressed the principles of the Data Protection Act; clarification was needed regarding the retention period for the data and what numbers would be necessary for the study. Section 16 of the application referred to arrangements made to consider applications from researchers to access the data. Members expressed concern as the application did not specify on what grounds this would be acceptable.

The Committee provisionally approved this application. The provisional approval was subject to the following conditions:

1. That the support would be given to cover the retrospective data, and not for prospective data. Prospectively, consent should be sought, dissent must not be overridden and the consent of non-respondents must not be assumed.

2. Clarification to be provided over the retention period for the identifiable data items

3. Initial contact should be made by the relevant hospital or GP

4. Confirmation as to how consent/dissent would be recorded

5. Confirmation of the size of the cohort.

6. Progress on suitable user engagement to be reported in the annual review

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

vi. West Yorkshire Primary Percutaneous Coronary Intervention (WY-PPCI) Outcome Study ECC 3-06(f)/2009

Leeds Teaching Hospital NHS Trust submitted an application for section 251 support for a prospective and retrospective follow-up study on outcomes from patients who had suffered

heart attacks. The application was for retrospective cohort patient information in order to contact them and seek consent to participate. The study aimed to evaluate the impact of small/new changes in clinical practice and subsequently improve the current clinical service.

Members agreed that the application purpose was worthwhile; however, Members were concerned at the unfavourable opinion given by the REC. In line with the Health Service (Control of Patient Information) Regulations 2002, any section 251 support is restricted to that approved by the relevant Ethics Committee. It was noted that this application would be re-submitted to the REC on 01 June 2009. As such, the Committee agreed to defer this application to its next meeting on 20 July 2009 pending a favourable opinion from the REC.

The Committee recommended the following actions for the applicant:

1. Applicant to provide copy of REC letter to NIGB Office (electronic and hard copy) following ethical review on 01 June 2009. Once received, required actions to progress to the Committee would be made

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

Action: Clarification to be provided about the distinction between RECs and Ethics

vii. Pilot study to determine the validity of Hospital Episode Statistics data on the prevalence of Recurrent Respiratory Papillomatosis in England ECC 3-06(g)/2009

This application from North Bristol NHS Trust required section 251 support to access HES and medical records in order to identify and classify a cohort for their study. The prevalence study aimed to determine the number of children suffering with paediatric respiratory papillomatosis (benign laryngeal growths) in England.

On balance, the Committee agreed that support would be provided for access to HES, however, Members were not persuaded that there was sufficient justification to enable support for researcher access to medical records without consent. As such, Members requested that once the local patient identifier had been obtained from HES, the option be explored for the relevant consultant to send a letter to the patient on the researcher's behalf inviting them to take part. If this should this not prove practicable, then further evidence and justification should be provided to the Committee for further consideration

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

viii. Developing a basis for family interventions for childhood appearance distress: The role of family processes and shame in the psychosocial adjustment of children with visible differences ECC 3-06(h)/2009

The purpose of the application from the University of West of England was to identify a cohort for their study using GP databases and write to them directly to seek consent. The cohort would include children aged 8-11 and would include children with common health conditions, differences in appearance and a control cohort with no visible difference. The study aimed to assess whether psychosocial outcomes of children with visible physical differences were dependent upon variability of family profile.

After discussion, Members agreed that, for the purposes of section 251, psychosocial adjustment fell within the terms of medical research and agreed that the study's purpose would add value to the body of knowledge in this area.

Concern was raised over the methods that the researcher proposed to use. Discussion took place about whether a more appropriate method could be used rather than the researcher having direct access to GP records. In this instance, the Committee agreed that utilising an alternative approach would negate the need to resort to section 251 support. Members considered the size of the cohort and number of practices involved to be a manageable number in which to pursue an alternative approach than that stated in the application. It was highlighted that section 251 support could only be granted as a 'last resort' where consent was demonstrated to be not feasible and where anonymised information would not suffice.

Members suggested that if the applicant was aware of the read-codes then these could be provided to the GPs. It was recommended that negotiation take place with the GPs at each practice to provide them with the read-codes so that they are able to identify the cohort on the applicants behalf without disclosing the patient identifiable information. The GPs could then be provided with the necessary consent information in sealed envelopes so that the GP could label and send on the applicant's behalf. Any responses could be provided back to the applicant directly. Following this approach would mean that there would be no disclosure of patient identifiable information outside of the clinical care team, and therefore no need to seek section 251 support.

Members also discussed and agreed that the patient leaflet pitched at ages 8-11 appeared to be targeted more at an adult audience and recommended simplifying this leaflet.

The Committee concluded that it would not be appropriate to resort to use of section 251 support to carry out the study, as a different method could be used to negate the need for this support.

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

ix. Trends in the incidence and associated factors for childhood intussusception ECC 3-06(i)/20089

This application from UCL Institute of Child Health aimed to obtain an estimate of the occurrence of intussusception (obstruction of the bowel) and related factors among infants in England. The purpose of the study was to provide a more accurate, current estimate of the occurrence, the last study having been over a decade ago, and also to provide trends of occurrences over the past fourteen years using HES data. Section 251 support was requested to allow access to HES data for linkage with BPSU surveillance data.

Members were sympathetic to this study into this rare condition and appreciated that consent would be hard to obtain as the information was retrospective. The application required HES data over a significant period of time which was recognised as an additional factor that made consent impractical. The Committee were therefore persuaded by the arguments set out in the application explaining why section 251 support was required. Members additionally considered whether date of birth was necessary rather than month or year of birth, but they agreed that this identifier would be required for the purposes of the study.

The Members provisionally approved this study. This provisional approval was subject to the following condition of approval:

1. Members requested that there be greater user involvement and that there is engagement with appropriate groups which is to be set out in the annual review

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

x. Sheffield Sarcoma Archive Analysis: studies in the molecular pathogenesis of soft tissue sarcomas ECC 3-06(j)/2009

The purpose of this application from the University of Sheffield was to carry out a laboratory based study of archived pathology material on rare malignant tumours in order to identify contributory factors. Section 251 support was required to access medical records to enable correlation with laboratory findings.

Members were sympathetic to the purpose of this application and noted that as a whole, the application was generally well put together. After some discussion it was agreed that consent would not be appropriate in most instances as the cohort would have died, however where the patient was still alive consent should be obtained. Where the patient was deceased pseudonymised or anonymised data was deemed most appropriate as Members were mindful of the sensitive nature of the information.

The Committee felt that the application was unclear whether tissue samples of the cohort related entirely to the deceased, and whether the tissue samples had been collected prior to 01 September 2006 (existing holdings), therefore the Committee agreed that the applicant should respond satisfactorily to a number of queries prior to issuing final approval.

The Committee were also mindful of the implications of the Human Tissue Act 2004, which fell outside of the Committee's remit. The Committee agreed that it was important for the applicant to seek further advice on the Human Tissue Act 2004 and the implications this may have on the study. Members indicated that the remit of section 251 did not extend to providing support for access to tissue samples, but it could be used to provide support for the processing of the data obtained from the tissue samples.

The Committee approved this application, subject to satisfactory responses to the following points of clarification and conditions of approval:

Clarifications to be made by the applicant:

1. Final confirmation over who would be carrying out the accessing of the pathology database and tissue samples

2. Further explanation whether the study would use existing holdings (samples obtained prior to 01 September 2006), or whether it would access tissue samples stored after this date

3. Clarification as to the date ranges of the archived tissue material and whether the samples would relate purely to deceased persons or whether some of the cohort would still be alive

4. In response to question 9-2 on page 7 of the application form and the section around the three databases, Members noted the detail on the third database holding the linked unique study number to the hospital record and queried why the Chief Investigator required access to this. Members requested reasons on why this could not be held by the collaborating pathologist.

Conditions of approval:

1. Where the tissue samples related to the living, consent should be obtained for the use of these tissue samples. If the samples related to the deceased then this information should be pseudonymised or anonymised prior to any disclosure to the researcher.

2. On the basis that the collaborating pathologist would identify the cohort in order to obtain the tissue samples, the researcher would not have access to the tissue samples until the data extraction is complete and therefore would be in receipt of pseudonymised data only

3. As the use of tissue lay within the remit of the Human Tissue Authority, the researcher was strongly advised to take separate measures outside of section 251 approval to ensure that they would be fully compliant with the requirements of the Human Tissue Act 2004.

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

xi. UK Brain Archive Information Network (BRAIN UK) (Existing Holdings) ECC 3-06(k)/2009

The University of Southampton submitted this application for section 251 support to establish a research tissue database used for the purpose of allowing researchers to identify participating centres that held relevant tissue samples. The database would enable researchers to identify centres that held tissues of use to them and their studies. The applicant had submitted this application with a view to asking the Committee's opinion on this database.

The Committee noted that in most instances identifiable data would not be required as health professionals in participating centres would identify relevant information and transfer pseudonymised data to the applying organisation. However section 251 support was requested as the application indicated where local time and resource constraints were limited then a BRAIN UK member would be made available to undertake the local identification on the participating centres' behalf. This would be a secondary measure undertaken only where local resources were not available.

Whilst supportive of this application, the Committee expressed reservations over this secondary measure. It was agreed that this was too general a criterion a lack of local resources could be frequently cited, and as this was potentially broad in scope it meant there would be significant potential for an unspecified amount of access by an external researcher to patient identifiable information without consent. The Committee referred to previous applications where this situation had occurred and agreed that because section 251 support is a last resort it could not be granted, at this stage, for this secondary measure.

Section 251 support would be required if the initial identification were to be carried out by anyone other than the relevant healthcare professional at the local level. Should the situation arise where a member of BRAIN UK would be asked to carry out the identification, then section 251 support must be sought prior to any such identification; providing evidence to justify this support.

The Committee identified the following further actions for the applicant to take.

1. In instances where a BRAIN UK staff member was asked to carry out identification on the participating centre's behalf, then section 251 support must be in place prior to this taking place. An application setting out the reasons for this and providing specific evidence, based upon the problems experienced, must be submitted to the Committee.

2. The application was informed that the precise legality of the use of tissue lay outwith the remit of the Ethics and Confidentiality Committee. Whilst the Committee has remit to assess the processing of the data (in the context of the Data Protection Act 1998) definitive advice should be sought from the Human Tissue Authority to ensure that they were fully compliant with the Human Tissue Act 2004

Action: NIGB Office to notify applicant of Committee decision.

xii. Retrospective analysis of Quantiferon results in patients being investigated for active TB in Central Manchester and Manchester Children's NHS Trust ECC 3-06(I)/2009

The purpose of this application from Central Manchester and Manchester Children's Hospital NHS Trust was to measure the sensitivity and specificity of the QuantiFERON Gold Test in patients with suspected active TB, using retrospective data. Section 251 support was required to allow access to medical records in order to identify clinical history and evidence of TB and response to treatment.

Members were informed that the application had been submitted via IRAS in January 2009 and it was received by the NIGB Office at this time but, due to an oversight, had not been seen by the ECC. The applicant had asked about the progress of the application after the deadline for papers for the May meeting and was informed about the error. In the interests of attempting to progress the application, it was submitted to the meeting, despite the fact that there were a number of inconsistencies and issues around the application which due to the timescales involved, could not be addressed satisfactorily in time for the papers to be sent to Members.

The Members agreed that this was a worthwhile study and were supportive of the purpose of the application. However the Committee felt that the consent questions on the application form had not been sufficiently addressed and Members expressed concern that the application did not include satisfactory reasons for not gaining consent. Section 251 support would only be available where the applicant had shown that anonymised data was not sufficient and that consent was not practicable.

Concerns were raised over the sexual health data that was requested in the application. The Committee requested that the applicant be made aware of the implications of the Sexual Health Directions that govern the use of sexual health data for research purposes.

Due to these reasons, the Committee were unable to provide section 251 support to this application, due to the incomplete nature of the form and the ambiguity that arose due to this. They advised that an accurate, fully completed and revised application be resubmitted to the Committee so that it could be discussed at the next meeting.

The consideration points for revised application were highlighted as:

1. Clarification as to whether year of birth would suffice as an identifier rather than date of birth

2. Question 9-2: the application stated that consent would not be applicable as the research was retrospective and patients had been consented to the test. The issue was whether the patients had provided consent for their data to be used for research purposes. The assumption was that they have not, therefore it was inaccurate to state that consent would not be applicable

3. Clarification over whether the Chief Investigator and other named researchers had been responsible for the clinical care of the cohort. If not, this would involve a disclosure of confidential patient information to individuals outside of the clinical care team and it was this disclosure that would need to be justified

4. The application would need to explore previous attempts made to seek consent, and evidenced justification as to why attempts have not been made, particularly considering that some patients would already be under the care of clinicians for the management of TB. An exploration of why treating clinicians could not seek consent on the applicant's behalf should be addressed.

5. Question 15-1 on user involvement has not been addressed and did not constitute user involvement in terms of involving patients, therefore this would need to be significantly revised

6. The application needed to reflect an awareness of the 2000 Sexual Health Directions that govern the use of this type of data for research purposes

7. Further clarification over the classes of support requested should be amended to accurately reflect the classes required

8. Question 29 should be revisited to confirm that there would be access to patient identifiable information outside of the clinical care team

9. Significant revision was required of the responses on how the study would meet the requirements of the Data Protection Principles.

10. The date of the Data Protection expiry period required updating.

In particular, the areas and sections around consent needed to be considerably strengthened, in addition to that of user involvement.

Action: NIGB Office to inform applicant of Committee decision.

xiii. Prognostic Factors in Prostate Cancer for patients treated by watchful waiting ECC 3-06(m)/2009

This application from Cancer Research UK was for a retrospective population based study to be carried out in patients registered on UK regional cancer registry databases who have had prostate cancer diagnosed between 1990 and 2003 inclusively. Support under section 251 was requested as patient data would be collected from hospital medical records and analysed to evaluate the prognostic value of specific factors on progression in men with clinically localised prostate cancer.

The Members were supportive of this study and agreed that consent would be difficult to obtain as the cohort was large and many would be deceased. However Members felt that

current plans for user involvement were not satisfactory and noted that there were many prostate cancer charities that could be approached if it was not feasible to approach patients themselves.

Members did raise the issue of genetic data and discussed the issue of germ-line mutations in the context of the application. It was agreed that where research could possibly reveal germ-line mutation, consent or anonymised data should be used.

The application was provisionally approved subject to the following conditions:

1. Contact and engagement is to be carried out with a Prostate Cancer Group or relevant support group, and this should be incorporated into the annual review.

2. There should be no undertaking of any activity that reveals germ-line mutation without either consent or anonymisation of the data.

Action: NIGB Office to inform applicant of Committee decision.

7. Any Other Business

7.1 Public Interest Disclosure Guidance [ECC 3-07(a)/2009]

This paper arose from a discussion at the NIGB. This draft guidance supplemented the NHS Code of Practice on Confidentiality and set out a number of suggested case studies to aid front-line staff when assessing public interest considerations in the context of disclosure of patient identifiable information without consent. The NIGB had requested that the Committee consider and feedback their views to the NIGB.

Members agreed that, due to the importance of the draft document, more time was needed to consider the guidance and a full discussion should take place outside of the typical meeting schedule so as to ensure scheduled meetings focused upon applications.

Action: Separate meeting to be arranged to discuss guidance and feedback views

7.2 Annual Review of Regulations

The NIGB IG Lead presented a paper setting out options for the annual review of the regulations to assess whether they remained fit for purpose and whether any amendment would be required. These are required to be reviewed annually by the Committee. Due to time constraints it was agreed that this item would be considered at the separate meeting alongside the Public Interest Guidance. The Members agreed to continue with the regulations in their current form until this further review had been carried out.

8. Future Meetings

- July – Monday 20th 2009
- September – Monday 21st 2009
- November – Tuesday 24th 2009