Meeting held on Tuesday 27th January 2009

Present:

Members: Professor Dame Joan Higgins (Chair), Mrs Pauline Brown, Professor Mike Catchpole, Dr Fiona Douglas, Ms Stephanie Ellis, Mr Michael Hake, Professor Sir Denis Pereira-Gray, Mr Terence Wiseman.

External visitors: Dr John Parkinson (item 6 ii), Ms Helen Laing and Mr Martin Old (item 6 iii).

In attendance: Ms Victoria Cox (*Deputy Policy Manager*), Ms Natasha Dunkley (*Approvals Manager*), Mr Paul Eveson *(Department of Health),* Ms Melanie Kingston (*Approvals Officer*), Ms Zoë Lawrence *(NIGB Business Manager)* and Ms Karen Thomson (*NIGB IG Lead*).

1. Welcome and Apologies for absence

1.1 Apologies for absence were received from Dr Patrick Coyle, Dr Tricia Cresswell, Ms Ros Levenson, Professor Roy McClelland, Ms Sue Parroy and Dr Mark Taylor.

1.2 It was noted that Ms Barbara Meredith and Dr Peter Rutherford had elected not to continue their membership to the Ethics & Confidentiality Committee. The NIGB Business Manager confirmed that an appointments process would shortly commence to appoint two NIGB members to become members of the ECC.

1.3 **Declaration of Interests**

Ms Ros Levenson declared an interest in agenda item 5 NCASP Pulmonary Hypertension [PIAG 5-06(f)/2008] in her role as a member of the National Commissioning Group which commissions pulmonary hypertension services.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on 08 December 2008 [PIAG 6-02/2008] were agreed to be an accurate record, subject to minor amendments. It was agreed that the applying organisation names would be added to the December minutes and all subsequent Committee minutes.

Action: Secretariat to add organisation name to December and prospective minutes

3. Matters Arising / Action Points:

i. Secretariat report

The Secretariat report [ECC 1-03/2009] was received and its contents noted.

Biobank complaint

A complaint had been sent to the Patient Information Advisory Group from a member of the public who had been contacted by UK Biobank and invited to participate in their research. The complainant had the impression that PIAG stored her data and had shared it with UK Biobank without her consent. The Secretariat had explained that PIAG held no data at all but that Section 251 support had been provided for UK Biobank to access demographic and administrative data (not clinical data) to enable invitations to be issued to members of the public to participate in their research. When Biobank wished to have information on the health or clinical history of participants then consent was always sought.

The Committee agreed that it would be appropriate to contact UK Biobank in order to ensure that the complaints process was clear to members of the public.

Action: Secretariat to contact UK Biobank about complaint handling

Healthcare Commission Information Governance Meeting

The Secretariat attended a meeting at the Healthcare Commission to discuss the arrangements and transferral of HES data ownership with the forthcoming merger to the Care Quality Commission.

Members asked for a briefing note to be produced on the Care Quality Commission to include details on the bodies that merged and its responsibilities.

Action: Secretariat to produce briefing note on role of CQC for distribution to Members

IRAS update

The Secretariat reported that work is continuing to prepare IRAS to reflect the changes from the Patient Information Advisory Group to the Ethics and Confidentiality Committee. This would include updating references to section 60 to section 251 where appropriate. It was reported that the fixes arising from the original implementation would be incorporated into the NRES work schedule from March onwards. Current indications were that incorporation of the MRIS form to IRAS would be provisionally scheduled for the end of the year.

ii. Chair's report

NHS Constitution

The Chair noted that the NHS Constitution had been published and the section which had concerned PIAG, about access to medical records by researchers outside the clinical care team, had been removed.

Administrative Review

Members noted that the review had commenced and the NIGB Business Manager would be managing the process. It was made clear that the review would not be looking at decisions taken by the Committee and would focus upon the administrative processes, taking into account stakeholder views in order to identify improvements.

ECC Chair and membership

The Chair updated the Committee on the membership of the NIGB and the Chair of the ECC. It had been agreed that the ECC Chair should, as the Committee had proposed, be a full member of the NIGB, in order to ensure proper accountability and good governance. The Chair confirmed that she had been appointed, on an exceptional basis, as a full member of the NIGB for a twelve month period in order to ensure effective governance during the transition period. It was noted that this would not set a precedent for any other Committees that might be established within the NIGB.

The Chair thanked Members for confirming their preferred length of terms of office. It was noted that a similar process would take place for the Database Monitoring sub-Group once the Committee's arrangements and Terms of Reference (ToR) had been finalised.

Action: NIGB Business Manager to formalise the length of terms of appointment for Committee Members and subsequently review the ToR and membership of DMsG.

iii. Actions arising from the away day

The Chair thanked all members who attended the NIGB away day and sought views on the day. It was noted that useful discussions had taken place in identifying what the Board required from the Ethics & Confidentiality Committee and vice versa. One suggestion from the away day was to hold a conference on consent practices to aid awareness-raising of expectations around the use of patient identifiable information within research.

Another matter arising from the away day was the need for an official and published complaints and appeals process. Members noted that complaints were typically opportunities for further learning and there should be a formal process in order to extract and implement key learning points as part of an effective governance process.

Action: NIGB Business Manager to liaise with DPG over complaints and appeals process

Members concluded by agreeing that it would be helpful for membership of the Committee to include members from the National Information Governance Board.

4. Ethics and Confidentiality Committee Draft Terms of Reference [ECC 1-04/2009]

Members discussed and provided comments on the draft terms of reference that set out the expectations, remit and role of the Ethics and Confidentiality Committee.

The draft terms of reference with the Committee's comments would go back to the National Information Governance Board at its next meeting in February for final approval.

5. Applications previously considered

i. NCASP Pulmonary Hypertension [PIAG 5-06(f)/2008]

This application was a resubmission from the NHS Information Centre (NHS IC) and its purpose was to assess the quality of care, activity levels, access rates and patient outcomes on pulmonary hypertension at a national level. Support under section 251 was requested as the audit required access to identifiable information on adult patients diagnosed with pulmonary hypertension, prior to pseudonymisation.

The Patient Information Advisory Group had previously advised that the application be resubmitted as there had been limited evidence of suitable user involvement with no incorporation on how user views had contributed to the audit. The previous application did not provide sufficient detail on what would be audited and further work had been requested in relation to the responses to how the study would meet the requirements of the Data Protection Act 1998.

The Committee agreed that the NHS IC had demonstrated significant evidence of appropriate user involvement, taking into account the difficult condition being audited that carried a rapid mortality rate. Members also noted that the applicants had satisfactorily addressed the other points highlighted by the Patient Information Advisory Group; therefore the application was approved subject to the following conditions:

- Clarification over the retention period for identifiable data items.
- Members noted that the cohort was of a sufficiently manageable size in order to pursue pseudonymisation or consent, therefore a suitable exit strategy would need to be in place and evidence provided to demonstrate the steps taken to move towards this exit strategy in the Annual Review

Action: Secretariat to notify applicant of the Committee decision

6. New applications for section 251 support

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

No fast track applications were received since the PIAG meeting in December 2008

ii. Record linkage of GPRD data [ECC 1-06(b)/2009]

This application from the Medicines Healthcare Regulatory Agency involved an extension of a previous approval given by the Patient Information Advisory Group to use linked data to undertake drug, device safety and effectiveness research. Section 251 approval was requested in order to allow record linkage of General Practice Research Database (GPRD) data with cancer, hospital prescribing and orthopaedic implant data.

Although PIAG had provided support to a previous application, this application required more data items and linkage therefore the Committee agreed that it would be helpful to discuss these issues with a GPRD representative.

Following discussions, it was noted that the application did not involve any further identifiable data flows to the GPRD. Linkages would be carried out by the NHS IC, however, the NHS IC would receive patient identifiable data from the Registries in order to carry out the data linkages, and therefore the Committee noted there would be a slightly increased risk of identifiability. The Committee assessed the possibility of the potentially increased risk of identifiability against the importance of the activity and agreed that consent would not be practicable due to the numbers involved.

Members felt that that there should be a more systematic method to implement the right of patient opt-out as the use of leaflets giving details of the right of opt-out would not be sufficient to capture all relevant patients.. Members were pleased to note that the GPRD would advise general practices to place these details on their website, and that the GPRD would audit practices to ensure that they are allowing opt-out. The GPRD also agreed to issue reminders to practices to update their websites and leaflets in line with these comments. Members were also concerned that the patient leaflets did not make it explicit that there would be linkages with other data and recommended that these be updated to include these details.

The application was approved, subject to the following conditions:

- Support under section 251 would be given to link GRPD data with hospital prescribing data, cancer registry data and orthopaedic implant registers.

- Revision of practice leaflets to reflect the linkages with GPRD data in line with this approval, and active and demonstrable encouragement of the systematic use of the leaflets throughout practices via an evidenced audit process.

Whilst not a condition of approval, Members noted that greater involvement should be developed with the representative patient groups. Members agreed that more laypersons and patients could be involved, and this could be achieved through communications with Cancer Networks.

Members noted the increased amount of work with the NHS Information Centre (NHS IC) and agreed that it would be timely to meet with the NHS IC with a view to identifying appropriate provisions for support of their 'honest broker' role under section 251.

Action: Secretariat to notify applicant of the Committee decision
Meeting to be arranged between NHS IC and ECC

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

This application from the Healthcare Quality Improvement Partnership (HQIP) aimed to cover national audits in the areas of cancer, chronic heart disease, and diabetes in primary and secondary care. Support under section 251 was requested as responsibility for NCASP had transferred from the Healthcare Commission to HQIP on 1 April 2008. An annual review had not been submitted and approval had expired therefore a further application from HQIP as the data controller had been required. Representatives from the NHS Information Centre and HQIP attended to answer queries around the Programme.

The Committee welcomed the discussions with Martin Old and Helen Laing that helped to clarify some issues and aided the subsequent deliberations by the Members. Overall, Members were highly supportive of the purpose and critical nature of the application; however, due to a number of fundamental concerns, the Committee were unable to approve the application in its current form.

Members expressed concern that the application appeared to assume that the previous application should be extended rather than seeking to make use of developing technical solutions. Members were mindful of the fact that standards around information governance had changed significantly since 2003 when the first application had been made, along with a change in patient expectations as to how their identifiable information be used and shared. Consequently Members agreed that the whole application should fully reflect these changes.

The Committee expressed concern around the term "informed implied consent" as used within the application and were of the view this was a misuse of the term. Members noted that patients would be generally aware that clinicians should keep accurate and contemporaneous notes; however, the Committee did not consider that patients would be generally aware that national clinical audit takes place, nor that their personal data would be used for this purpose, therefore it would be inaccurate to state that patients have informed implied consent to participate in the audits.

The Committee noted the example cited to illustrate the practical issues around the seeking of express consent. Members felt that this was an extreme case and there were many more situations in which patients were willing and able to give consent.

Members also noted that there was little within the application to reflect the autonomous nature of patients and that they would have the common law right to object to any sharing of their identifiable information. Members expressed concern that there was limited evidence to show how this objection would be acted upon other than where there is a statutory basis

mandating disclosure, or the public interest disclosure would be sufficiently substantial to warrant over-riding any objection. Members noted the assertion in the application that there were currently no systems in the NHS to allow for consent for refusal to take part in audit to be recorded and acted upon. The Committee considered that whilst there is not a universal system to capture these details, in general practices there would be facilities to record when consent was withheld therefore the Committee did not agree with this assertion. Members agreed that this option should be explored or evidence provided to support this view.

Members noted and welcomed the support for the Care Record Guarantee (CRG) but were unable to identify clear support for the commitments and principles set out in the CRG in the actual application form, and agreed that this be reflected.

The Committee noted there would be moves to seek to improve information for patients to ensure they were able to provide informed consent. Members referred to the previous 2003 application and noted a lack of evidence within the application demonstrating significant attempts to address the consent issues in order to move towards an exit strategy. Section 251 is a temporary measure to allow organisations to move towards a consent model or the use of anonymised data therefore members agreed that there should be definitive evidence, with timescales, to illustrate how progress would be made towards reducing reliance on this temporary support.

The Ethics and Confidentiality Committee fully accepted and recognised the critical nature and importance of the audits. Due to this importance, Members requested that the application be re-submitted to the March meeting taking full account of the comments made.

Action: Secretariat to notify applicant of the Committee decision

iv. Parental report assessment for cognitive delay in at-risk infants [ECC 1-06 (d)/2009]

This application, from the University of Reading, aimed to test the sensitivity and specificity of a test for cognitive delay in at-risk children. Section 251 support was sought as the study required researcher access to patient contact details, the patient management system and medical notes on a rolling monthly basis in order to assess suitability for inclusion, and to invite the cohort to participate in the study on a retrospective and prospective basis.

Whilst supportive of the purpose of the study, the Committee was unable to provide section 251 support for the application on the basis that the relevant consents could reasonably be sought by the clinicians involved. Members noted that member of the clinical team would initially identify the cohort, and at a later time period, a member outside of the clinical team would assess the notes and systems to check that the cohort would still fit within the criteria of the research. Members were therefore not persuaded, in this instance, that there was sufficient justification to temporarily lift the common law duty of confidentiality to allow researcher access to patient and family identifiable information as part of the proposed process for seeking consent, in order to mitigate the administrative burden on the clinical team.

Members recommended that it would be advisable to ask someone involved in the clinical care team to access and check through the notes for the relevant information. The clinician could subsequently write to the patients and inform them that they would contact them again

within a specified period of time, thus allowing the right of patient opt-out. If the patient felt this would not be appropriate the patient could subsequently write back. Alternatively, a member of the clinical team could again identify the cohort, and write to the patients seeking permission for the researcher to have access to the patient notes. Members were also of the view that it would not be necessary to view the medical notes to identify mortality as this information would be available elsewhere.

Action: Secretariat to notify applicant of the Committee decision

v. Molecular characterisation of paediatric myelodysplastic syndromes [ECC 1-06 (e)/2009]

This study at Great Ormond Street Hospital was to retrospectively identify, at diagnosis, children with leukaemia likely to do well without bone marrow transplantation. Support under section 251 was requested as the study required retrospective access to DNA, and a case note review of children diagnosed with leukaemia over the previous fifteen years.

Members were supportive of the purpose of this application; however, Members agreed the use of section 251 support would not be appropriate in relation to this study. The rationale for this decision was based upon the principle that the patient identifiable information required would be obtained as part of normal clinical practice, and that the researcher would have access to the patient information as part of their normal clinical duties. As such, there would be no disclosure of confidential patient information outside of the clinical care team and section 251 support would not be required. Members noted that where the application requested access to tissue samples prior to 2006, section 251 powers could only be used to approve the processing of the samples, and not the initial consent. Members additionally advised that genetic testing should be carried out with adequate consent if the analysis could identify a mutation for which there could be a reasonable possibility that it is germ line. If the patient was deceased then Members advised that consent be sought from close relatives. The alternative would be to anonymise samples, provided that the anonymisation would be carried out by a member of the clinical team and to current accepted good practice in Clinical Genetics.

Action: Secretariat to notify applicant of the Committee decision

vi. Evaluation of group intervention for fire-setting offenders [ECC 1-06(f)/2009]

This study by the West London Mental Health Trust aimed to examine the effectiveness of an intervention in helping to reduce re-offending for male psychiatric patients with a history of fire-setting. Section 251 support was requested as the study required access, by a researcher not directly involved in the cohort's clinical care, to a central referral database in order to access patient identifiable information for the purpose of identifying and contacting the cohort for consent.

Members agreed that the purpose of the study would be of benefit, however, Members were unable to approve the application as it was considered to be an inappropriate use of section 251 powers. It was noted that the applicant had previously submitted a similar application and the same considerations would also apply in this instance. The study involved a very

small cohort and in such situations, it would be practicable for a member of the clinical team or the Responsible Medical Officer to seek consent on behalf of the researcher.

Members noted that it was likely that section 251 support would not be an appropriate mechanism where the cohort consisted of small numbers. It was advised that the Secretariat filter such applications accordingly, with the appropriate support from the Committee.

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

vii. Trial of a new PCR system for detection of bacteraemia [ECC 1-06(g) /2009]

The purpose of this application, from Guy's and St. Thomas's NHS Foundation Trust, was to carry out a one month trial to investigate the use of a test in order to identify the specific type of bacteria/fungus in sepsis patients. Support under section 251 was sought as the trial required access to blood samples in order to assess the test.

Members were supportive of the purpose of the application as it could help improve patient outcomes including a reduction of mortality due to sepsis. It was not apparent within the application whether the applicant was a member of the direct clinical care team, therefore Members advised that if the applicant was a member of the clinical care team then there would be no disclosure or subsequent breach of confidentiality, and section 251 support would not be required.

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

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

The aim of this study, from the University of Leeds, was to create a dataset for the North of England on specific cancer incidences. Support under section 251 was required as the study required access to HES data and cancer registry datasets from 2000 – 2006 to examine inequalities, the impact of travel time and identification of a definition of survivorship using clinical attendance patterns.

Members noted that this was an important study, however, a number of key questions typically populated within the IRAS form appeared not to be present on the application. Due to this missing information, Members agreed to provisionally approve the application, subject to satisfactory responses to the following:

- Whether the applicant had tested the acceptability of using patient identifiable data without consent?

- An explanation as to why it would not be practicable for either the researcher's organisation, or the current holder of the information required by the researcher, to seek or obtain patient consent for the proposed use of patient identifiable information?

- Resubmission of the response given to the sixth data protection principle to accurately reflect the rights of data subjects

- Members agreed that to ensure appropriate user involvement the researcher should approach their local Cancer network in order to progress this aspect

Action: Secretariat to test whether a fix is required within IRAS
Secretariat to notify applicant of the Committee decision

ix. Experiences of survivors of Stevens-Johnson/TEN syndrome

This qualitative study from the University of Birmingham aimed to carry out a series of interviews with patients diagnosed with Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) in order to improve the future management of patients diagnosed with SJS/TEN and similar conditions in the future. Section 251 support was requested as, in order to identify potential participants, access to an existing database by a staff member outside of the clinical team would be required for the purpose of contacting the cohort.

Members noted that the study required access to a very small number of patients due to the rare nature of the condition; therefore the Committee considered that the study could be carried out without the use of section 251 support. Members agreed that access to the database in order to identify the cohort should be carried out by a member of the clinical team, and that contact should be made via the treating clinician in order to enable consent to interview.

Action: Secretariat to notify applicant of the Committee decision

7. Any Other Business

7.1 Coroners and Justice Bill

Members discussed a background paper that provided a brief summary of the key provisions of the Bill (Appendix A). It was noted that the NIGB Information Governance Lead would be providing a formal update to the Board on 18 February 2009.

The Committee emphasised that they fully supported the need for information sharing, in the right context, provided that it had the appropriate safeguards and scrutiny. Members also recognised that information sharing is justified and essential to carry out many activities. However, Members agreed that an information sharing order should not be used to overcome administrative inconvenience or be used as a shortcut.

Members were concerned that a potential consequence of the Bill would be that it could lead to a restriction of the amount of information a patient might share with their GP. If personal medical details could be made available to different agencies, without consent, the patient

might choose to withhold important information and this would be detrimental to the overall purpose of the NHS in improving health.

Members expressed concern over some of the terminology and agreed that some of these terms should be clearly defined. Members were also concerned that an information sharing order could be granted to achieve a "policy objective" and that this entailed a very broad power. The Committee highlighted that, in the three conditions for making an Order, there was a significant difference between "necessary" as compared to 'essential'.

Members noted that the ICO would assess an information sharing order to identify whether the order would be proportionate to meet the needs of the policy objective; however, there was a lack of detail as to how proportionality would be measured and there were various discussions as to whether this safeguard would be sufficient if it only looked at certain aspects of an Order.

Members also expressed concern that an implicit message within the Bill appeared to indicate that the need to share information in the public interest clearly outweighed the individual's interest in not sharing information. It was also not clear from the face of the Bill who would carry out this public interest test. Members commented that the public interest test contained within the Freedom of Information Act 2000, which required evidenced and detailed considerations of the arguments for and against disclosure in the public interest, appeared to offer a more robust mechanism than that in the present iteration of the Bill.

Members recommended that, whilst in the appropriate context information sharing is necessary and serves a valuable purpose, medical records should be removed from the scope of the Bill.

The Committee's comments would be forwarded to inform the NIGB's discussion on this issue.

7.2 Newsletter

The Secretariat asked for comments on the NIGB Office newsletter that had been circulated to all Members. This newsletter was designed to keep all Members of the NIGB and its Committees informed of the activities within the NIGB Office and to remind Members of specific points of contact for various workstreams. The Secretariat asked for any comments, improvements or further information to be fed back.

7.3 Date of further meetings

March 25th
May 21st
July 20th
September 21st
November 24th