# Meeting held on Tuesday 29th March

## Present

*Members:* Dr Andrew Harris (Chair), Professor Sir Denis Pereira Gray (deputy Chair), Mrs Pauline Brown, Dr Tony Calland, Dr Patrick Coyle, Dr Tricia Cresswell, Dr Fiona Douglas, Ms Stephanie Ellis, Mr Michael Hake, Dr Colin Harper, Professor Julia Hippisley-Cox, Professor Jane Kaye, Ms Sue Parroy, Dr Mark Taylor, Mr Terence Wiseman

*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)

## 1. Welcome and apologies

Apologies were received from Professor Michael Catchpole.

Professor Sir Denis Pereira Gray chaired the remaining new applications for section 251 support. Dr Andrew Harris took over chairing of the items that had been postponed from the 28th March meeting and any other business items.

## Conflicts of interest

Dr Tricia Cresswell declared an interest in item 4W as an employee of the Health Protection Agency, it was noted that she did not work directly with the study.

## 4. New applications for section 251 support

### 4S. National Hip Fracture Database – extension [ECC 3-04(s)/2011]

This application from the NHS Information Centre aimed to use case-mix, process and outcome data together with quality standards to improve the quality of care.

It was noted that this was an extension request to a previously approved application, and sought section 251 support to permit additional data linkage with HES for superspell data and to extend the approval period for a further year. Members commented that minimal identifiers should be used to carry out linkages. It was noted that some patient information had been produced but that this aspect could be improved.

Members noted that there had been limited changes from the previously approved application, and therefore approved the extension to include linkage with HES for superspell data, and extended the approval period for a further year.

**Action: NIGB Office to notify applicant of Committee decision.**

**4T. British Paediatric Neurosurgery Group (BPNG) Audit**

This application from the Society of British Neurological Surgeons set out the purpose of a national audit of paediatric neurosurgery to ensure that operations were carried out in a safe and sustainable environment. It facilitated the regular publication of results of surgery, which would help patients in the UK and abroad. It also potentially allowed for a rapid response to any practice which appeared to be generating unfavourable results.

A recommendation of support under section 251 was requested in order to provide a legitimate basis for the future processing of this dataset.

The Committee agreed that this was an important data set with a large number of public interest outcomes; therefore the Committee was keen to support this activity and to aid the applicant in seeking to provide a legitimate basis for its further use. Additionally, because of the importance of this audit dataset, the Committee considered it essential that it have a robust framework in terms of its information governance compliance.

When reviewing the application members noted that the database appeared to hold identifiable information about children without their parents' knowledge or consent. Members highlighted the importance of the Data Protection Act 1998 (DPA) principles and raised concerns that thorough consideration had not been given to these.

The Committee also noted the frank admission from the Royal College of Surgeons within the responses to Office queries that it was not aware of the Data Protection Act, and also that ignorance of the law was no excuse. Members suggested that the Royal College might wish to take legal advice on the implications of the DPA 1998 as the responsibility for complying with legal requirements and governance arrangements lay with the host organisation.

In line with the above, members reiterated that section 251 applications were required to comply with the DPA and therefore the Committee was unable to recommend support if the requirements of the DPA were not being met.

In addition to points raised over compliance to the Data Protection Act 1998, members raised further points for consideration by the applicant:

1. Members of the Committee queried whether the applicant had considered the possibility of moving toward using a system of obtaining appropriate consent.

2. The Committee queried the proposal within the application to retain data for the life time of the child. The Committee queried what proposals were in place for when the data subject reached adulthood and whether there was a possibility of retaining an anonymised data set.

3. The Committee queried the argument with the application for 100% ascertainment. It understood that power would be added by maximising numbers but the need for complete ascertainment would be required to be balanced in the public interest against any loss of confidentiality, and members agreed that it appeared that an evidenced case had not been made for this requirement.

4. Members were unable to identify the full list of data flows and requested that these be provided.

5. The Committee could not locate sufficient information to identify the full system of governance for the data base and asked for this to be clarified.

6. Members reiterated that they were only able to advise on data generated in England and Wales.

After careful review, the Committee considered that it was not in a position to be able to make a recommendation of support until it was satisfied that the requirements of the DPA 1998 were met and suitable responses had been provided to the requests for clarification.

The Committee highlighted that they were supportive of clinical audits of this kind and that highly valuable information could be obtained from it. Therefore the Committee agreed that in order to facilitate a re-application this would be able to be initially handled via the fast track procedure once the applicant had sought their own advice on compliance with the DPA, and clarified the data flows and information governance aspects. Members also offered to meet with the applicants in order to aid a resubmission and noted that similar issues had been raised when representatives of the Royal College attended the National Information Governance Board on 24th February 2011.

**Action: NIGB Office to notify applicant of Committee decision.**

**4U. British Paediatric Neurosurgery Group (BPNG) – HES analysis (ECC 3-04(u)/2011]**

This application from the National Cancer Services Analysis Team (NATCANSAT) set out the purpose of carrying out a comparative audit of the diagnosis and operation details recorded on the BPNG audit, against the equivalent details on the HES database, and also to enrich the BPNG database with additional information available from HES.

Section 251 support was sought in order to link the data to the HES database using the patients' postcode from HES data, in order to assess variations in the provision of paediatric neurosurgery across the UK.

It was noted that a recommendation of support would be dependent on the outcome to the application referenced ECC 3-04 (t)/2011 British Paediatric Neurosurgery Group.

As a recommendation of support was not provided to the BPNG application, the Committee was unable to consider this application or provide a recommendation. It was advised that this application should be submitted only when application 3-04 (t)/2011 had been reviewed and a recommendation of approval had been provided.

**Action: NIGB Office to notify applicant of Committee decision.**

**4V. End of Life Care Intelligence Network Care Homes Analysis (ECC 3-04(v)/2011]**

This application from the National Cancer Services Analysis Team (NATCANSAT) set out the purpose of understanding the profile of patients admitted to hospital to die from either home or care homes. This would be done by analysing the place of death, comparing patients resident in a care home with those resident at home, and identifying differences in the patterns of admission to hospital close to death.

It was noted that the the applicant was not requesting direct access to identifiable information, but for Northgate (who processed the Hospital Episodes Statistics (HES) database) to process information on their behalf to add a non-identifiable flag confirming if the patient was resident in a care home. As the applicant would not receive any identifiable data it would not be feasible to seek consent.

Members were supportive of this study and agreed to recommend approval under section 251.

**Action: NIGB Office to notify applicant of Committee decision.**

**4W. Toxoplasma pilot study [ECC 3-04(w)/2011]**

Dr Tricia Cresswell declared an interest as an employee of the Health Protection Agency and did not take part in the decision.

This application from the Health Protection Agency set out details of a case control study to identify risk factors of recent infection with Toxoplasma Gondii in England and Wales so as to aid public health interventions.

A recommendation under section 251 was sought to provide a legitimate basis for access to contact details of potential participants, which would be provided to the research team by the toxoplasma unit for cases and by referring laboratories for controls. In particular, access was sought for name and date of birth, and to address via the Personal Demographics Service (PDS). It was noted that the applicant had agreed that access to telephone number would not be received unless the participant had consented to provide this number.

The Committee noted that toxoplasma was a notifiable disease which was of importance as if the applicant intended to contact only cases, rather than controls, this could be carried out under the HPA's own powers as it was a notifiable disease. Based upon this fact, the Committee noted that receipt of case details would not require support under section 251, and could therefore proceed.

In relation to controls (those with a negative test result), members debated the feasibility of an alternative approach and understood that access to control data could not be carried out under the HPA's statutory powers. It was also agreed that there was no other practicable method in which to obtain the data other than via section 251 support.

The Committee therefore recommended approval under section 251, subject to the condition of approval.

**Condition of approval**

1. That the recommendation for support related only to controls, as cases could be accessed under the HPA's own statutory powers.

**Action: NIGB Office to notify applicant of Committee decision.**

**4X. An early warning system for identification and prediction of progression to multiple organ failure following major trauma [ECC 3-04 (x)/2011]**

This application from the John Radcliffe Hospital set out details of a database that would form the most complete patient record on the severely injured trauma patient in the UK. The aim of this database would be to provide the early identification of the patients at greatest risk, so that adjustments to their treatment to improve their chances of survival could be made.

Section 251 support was sought to permit collection of data on intensive care patients after major trauma, via software linked to monitoring systems. This data would be combined with details from the national trauma and intensive care databases.

The Committee noted that the cohort size consisted of approximately 1000 potential participants and that there had been good involvement in patient groups, which was to be commended. It was also noted that pseudonymisation and linkage data would be held by the clinical care teams so identifiable data would not be required after the database had been created. Members considered this to indicate good governance.

Members commented that the application was clearly constructed and noted that consent would be impracticable as it was a retrospective study and that the use of identifiers would be minimal. Members therefore unanimously agreed to provide a recommendation of support to this activity.

**Action: NIGB Office to notify applicant of Committee decision.**

**4Y. A follow up study of patient from the SEAS trial [ECC 3-04(y)/2011]**

This application from Merck, Sharpe & Dohme, and submitted by the University of Newcastle, set out details of a follow-up study to observe the incidence rates of cancer, total mortality, and mortality due to cancer over a 21 month period (from 04 March 2008 to 31 December 2009) in patients from the SEAS trial. An imbalance in cancer incidence had been observed between the groups, with an excess incidence being seen in the Simvastatin/Ezetimibe group compared with the placebo group.

Section 251 was required to provide a legitimate basis for the receipt of data from the cancer registries, and transfer of data already held by the applicant to the cancer registries. In particular, name, NHS Number, gender, date of birth, date of death, address and postcode were required for linkage purposes, and date of birth, date of death and gender would be required for analysis purposes.

The Committee considered this application in detail and discussed whether participants within clinical trials should be told if there was the possibility of potential harm arising from a trial. It was understood that some of the participants would have died and some would be alive, and the Committee focused upon whether it would be appropriate for support under section 251 to be provided to those who were alive, given that recommendations for support could only be provided where consent was evidenced to be unfeasible..

Members noted that according to the figures quoted in the application, there was a statistically significant increased risk of adverse effects associated with the simvastatin/Ezetimibe. It seemed to the Committee that this should be discussed specifically with the ethics/governance committee of the trial and it was not clear whether this discussion had taken place, therefore further clarification on this point was requested. Members raised the question of the living patients being informed, and whether it would be appropriate that living patients should be approached for consent on the basis that patients have a right to know if they were to be part of a trial.

Members noted that the intention appeared that the applicant did not wish to contact those who were alive until a risk had been confirmed, however, it appeared to the Committee that there was a statistically significant risk and therefore they were unclear as to why this sub-cohort could not be contacted for consent. The Committee were also surprised that this activity was not included within the original consent as identifying adverse events would be an important outcome for a clinical trial.

Based upon the considerations above, the Committee agreed to recommend support under section 251 to this study in relation to deceased patients only. However, members agreed that consent appeared to be reasonably feasible from the living, and therefore it was not considered appropriate to provide section 251 support to the living.

**Action: NIGB Office to notify applicant of Committee decision.**

**Items postponed from 28th March meeting**

**3C Secondary Uses Service (SUS) Annual Review follow up [PIAG 2-05(b)/2007]**

Members were provided with responses from the NHS Information Centre to queries that had arisen from the consideration carried out at the February meeting.

The responses to the queries were welcomed by the Committee. It was agreed that a recommendation of support would continue to be made to this application for a further 12 month period, however, this would be with the caveat that the Committee intended to further review the documentation outside the formal Committee meeting structure and any further queries would be forwarded to the applicant.

**Action: NIGB Office to notify applicant of Committee decision.**

**3D Palliative Care in Children and Teenagers with Cancer (deceased persons) [ECC 5-06(FT1)/2009]**

This application from the University of Leeds had been considered in 2009. The study had aimed to ascertain what proportion of children and teenagers who died from cancer in Yorkshire from 1990-2008 were referred to specialist palliative care services. The applicant wanted to link the data on two databases; the Yorkshire Specialist Register of Cancer in Children and Young People and Martin House Children's Hospice Clinical Database.

It was noted that following the application in 2009 the Committee had advised that the above referenced activity could take place using pseudonymised data, and therefore section 251 support would not be required. The applicant had submitted a letter seeking clarity over this decision, and a journal article that provided details of a similar activity that the cancer registries had carried out under the Health Service (Control of Patient Information) Regulations 2002. This letter put forward the view that the activity carried out by the registries was similar to the application previously rejected by the Committee.

In reviewing the original application, as no details of the application had changed and as it had been feasible for the activity to take place using pseudonymised data, the Committee agreed that a review of that decision could not be considered further. Section 251 support could only be provided where consent or use of pseudonymised data was not sufficient to achieve the aims of the activity

Members reviewed the copy of the publication mentioning the Thames Cancer Registry and understood how the issue and request for clarification had arisen. However, in relation to the status of the applicant and their access to cancer registry data, it was noted that in effect, the applicant would have taken data from Martin House and the cancer registries, transferred it to the Paediatric Epidemiology Group and carried out other activities on the dataset. This data flow was considered to fall outside the normal activities of the registries.

The Committee remained of the view that this approach deviated from the cancer registries specific support and therefore any such applications would require a legitimate basis other than relying on the support provided to the registries.

Members advised that if all analyses were carried out by the cancer registries, then this would be within the terms of the registries own support and an individual application would not need to be submitted to the Committee. However, exporting patient identifiable data to a third party, such as the applicant, would not be covered by the Registries support.

**Action: NIGB Office to notify applicant of Committee decision.**

**Dr Andrew Harris resumed as Chair for the remainder of the meeting.**

## 4B. Community Datasets – extension to SUS [ECC 3-02(b)/2011]

This application from the NHS Information Centre set out details of the processing of Community Services data as part of the Secondary Uses Service. The Community Information Data Set (CIDS) was a new data set that had been commissioned by the Department of Health as part of the Transforming Community Services Programme. It was indicated that the purpose of an additional dataset would support the collection, collation and reporting for community services commissioned under the NHS Standard Contracts.

Section 251 support was requested to enable the disclosure of patient identifiable data from care providers to the Department of Health (DH) (in the form of SUS). Extracts of the CIDS from SUS would be made available in pseudonymised form via a single pseudonymised extract of data out of SUS to the NHS Information Centre.

In reviewing this application, Members were of the view that this represented a change from service-centered data collection, to a data collection that was patient focused. Members noted that this activity required access to NHS number, local patient identifier, date of birth and death, postcode, ethnicity, disability and other clinical and activity items, and that consent was not considered to be feasible due to the large numbers involved. Members also noted future plans to provide identifiable data to commissioners, and welcomed the clarification that any intention to pursue this option, or to change the arrangements within the application would be subject to a separate or amended future applications and therefore these aspects were excluded from scope of the current consideration.

Members were broadly supportive of the application; however they agreed that there were several issues which required clarification before a recommendation of support could be made.

Members were of the view that the purposes were broad in scope and that it was difficult to identify the precise purposes for which the data would be used. In line with this, Members requested further clarity over the specific purposes and outputs of the data collection, including precisely who data would be shared with and the definition of anonymisation and pseudonymisation used within the application. Members also sought further detail on the proposed benefits to this activity, which should be clearly linked to the purposes and the collection of data at a national level.

When reviewing why consent was not considered feasible, the main argument advanced was that local systems did not have the capability of recording dissent. Members were of the view that this did not appear to be an appropriate reason for a recommendation of support under section 251, and did not directly address the issues of seeking consent. Members therefore requested clarification on why consent was considered to be impracticable so as to provide a clear justification for support under section 251.

Members could not identify an exit strategy from the processing of data under the remit of section 251. It was indicated that recommendations for support under section 251 were meant to be temporary, with the expectation that either a consent-based approach, or reduction of identifiability, or a combination of both should be pursued. In line with this, further details and timescales were requested on an appropriate exit strategy.

Members felt that more clarity should be provided in order to demonstrate compliance with the Data Protection Act 1998 in the context of the application. In particular, timescales over retention of identifiable information was requested, although members agreed that all responses should be reviewed and revised to demonstrate compliance.

The Committee noted that the dataset included other personal details, such as employment, and indicated that caution should be exercised as the combination of other data items could render this

identifiable in smaller communities. Further clarity was requested on how this possibility of inferential risk would be managed.

The Committee agreed that they were not in a position to provide a recommendation of support at the meeting, and therefore agreed to defer the application until satisfactory clarifications of the above had been received. It was agreed that the responses could be considered outside the Committee meeting via the fast track procedure.

**Action: NIGB Office to notify applicant of Committee decision.**

## 5. Presentation on the Regulation and Governance of Health Research

Marc Taylor, Deputy Director of Research and Development at the Department of Health, attended to present to members the proposed framework for research regulation and governance in the future.

Members were informed that it was proposed, following the Academy of Medical Sciences review, that a central research regulator would be established as a Special Health Authority by Autumn 2011. This would initially include the National Research Ethics Service and eventually the functions of the ECC could be included within the regulator.

Members raised concerns that the research regulator would not be seen as independent, like the ECC, and therefore would lose patient's trust. Members were informed that the research regulator would remain separate from the Department of Health and that it was the intention that it would become more visible to patients and easier to understand.

## 6. Introduction to NIGB Applications Database

Melanie Kingston, Deputy Approvals Manager, provided an introduction to the NIGB Applications Database and its functions. It was noted that this would be ready to accept applications in relation to non-research activities in April 2011. Members were informed that the full launch date would be dependent upon technical linkages with the IRAS system.

## 7. Any other business

### Policy on medical students

Members were provided with a paper outlining a proposed position with regard to medical students undertaking studies as part of their training and the requirement for section 251 in these situations. Members agreed that medical students were by definition, doctors in training and that learning a complex job required all main parts of that job to be studied and practised. One aspect of this was working with confidential information and the laws and guidance which govern disclosure of that information. The Committee also discussed that the British Medical Association regarded students to be part of the medical team and that the General Medical Council could hold them accountable for their actions.

It was noted that arranging for students to take part in research or audit projects was common and encouraged by senior clinicians, universities and professional bodies. Additionally the Committee recognised that the number of medical students within the UK had sharply increased in the last decade and that a large number of these would already be involved in various audits within general or hospital practices being commonly regarded as a members of the clinical care team.

When students undertook audits they would be under the supervision of the clinician in charge and therefore it was discussed that they would remain fully responsible and should ensure that law and guidance in relation to confidentiality was followed.

The Committee agreed that:

1. That medical students attached to a senior clinician (consultant or general practitioner) should be considered part of the clinical care team when contributing to audit or research.
2. That the senior clinician would remain responsible for both the research or audit and the handling of confidential information in medical records.
3. That it would not be necessary for an application for section 251 support in these situations.

**Access to MRIS death data**

It was agreed that applications for MRIS death data (date and cause of death) from clinical care teams, in order to carry out audit or research projects in their service, would not require an application for section 251 support. Members agreed that consent could be reasonably implied for this disclosure to clinical care teams and noted that the data would be in the public domain. Where data was required locally by those with legitimate access to patient records members agreed that the initial data transfer should take place between MRIS and the clinical care team, and that the data could then be included in the patient's records so those with legitimate access could use for secondary purposes.

**Establishing policy on access to deceased persons data**

The Chair advised the Committee on a piece of work that was required in relation to clarifying the Committee's position on access to deceased persons data. Members discussed that further information would be required in relation to how long the duty of confidentiality lasted after death and who would be considered the most appropriate person to approach for consent to access a deceased persons records.

Members agreed that a paper would be produced by the Chair drawing on relevant expertise from members.

**Action: Chair to produce paper establishing policy for consideration by the Committee.**

**8. Future meeting dates**

2nd June 2011

28th July 2011

27th September 2011