PIAG
1-02/2004

PATIENT INFORMATION ADVISORY GROUP

Meeting on 9 December 2003

MINUTES

1. Present

Members: Professor Joan Higgins (Chair), Professor Michael Catchpole, Professor Sir Cyril Chantler, Dr Tricia Cresswell, Mrs Helen Darracott, Ms Barbara Meredith, Ms Julia Palca, Professor Sir Denis Pereira Gray, Ms Karen Thomson and Dr Michael Wilks.

In attendance: Mr Alistair Donaldson, Ms Diaine Jee, Mr Simon Old, Mr Peter Singleton, Mr Sean Kirwan.

2. Apologies

Apologies were received from: Mr Michael Hake, Ms Helen Miller, Mrs Shahwar Sadeque, Mr Martin Severs, Mr Patrick Coyle, Mr Phil Walker.

3. Minutes of last meeting

3.1 The minutes of the last meeting [PIAG 4-02/2003] that had taken place on 15 September 2003 were approved.

4. Matters Arising

Revised Section 60 Regulations

4.1 Mr Kirwan reported that the consultation on the draft revised regulations to be made under Section 60 had begun on 4 November and would finish on 30 January 2004. The consultation documents were available on the Department of Health's website on the consultations and Section 60/PIAG web-pages, and had been sent to all of the bodies invited to participate in the Section 60 consultation that had taken place in 2001. He informed the Advisory Group that the Secretariat would undertake the following tasks at the end of the consultation:

(i) Collate and summarise responses to the consultation;

(ii) Revise regulations as appropriate and to copy to members of the Advisory Group for comment;
(iii) If appropriate, submit the revised regulations for debate in Parliament (under the affirmative process these regulations would be debated in Committee in the House of Commons, and on the floor of the House of Lords).

Information Governance

4.2 Mr Kirwan reported that the ongoing reorganisation of the Department of Health had delayed work to develop guidelines on anonymisation. Mr Walker would update the Advisory Group at its next meeting.

ACTION: Mr Walker to report on the development of guidelines for the NHS on anonymisation at the next meeting.

PIAG Annual Report

4.3 Mr Kirwan reported that the PIAG Annual Report had been published on the Department of Health website in early November. Hard copies would be printed and distributed in the New Year.

Guidance to applicants for Section 60 Support

4.4 Mr Kirwan reported that drafting of the new guidance note that had been considered by the Advisory Group at its last meeting was near completion; amendments would also be made to the application form in order to obtain additional information from applicants on Caldicott issues and the practicability of using anonymised data. It was intended that the revised guidance note and application would be published on the Department of Health website as soon as possible after the meeting.

PIAG Communications

4.5 Mr Kirwan acknowledged that information about Section 60 and the PIAG available on the Department of Health website was out of date. He reported that the Secretariat had undertaken a review of this information and proposed to introduce a number of changes in the coming weeks.

4.6 Ms Meredith said that she felt it was important for the Advisory Group to develop a communications strategy in order to counter misconceptions about Section 60 and the Advisory Group's attitudes to medical research. The Advisory Group agreed with her suggestion that consideration should be given to developing an independent website for the Advisory Group and raising its profile through interviews and articles in health journals.

ACTION: Secretariat to publish up to date information about Section 60.

CHAI and PCT Access to Patient Records

4.7 Mr Kirwan reported that following concerns raised in Parliament during debate on the Health and Social Care Bill about proposed powers to allow CHAI access to patient identifiable information, Ministers had conceded that CHAI should develop a

code of practice on patient confidentiality and that the Advisory Group should be consulted on its content. It had also been agreed that the Advisory Group should be involved in the development of a Code of Practice on PCT access to patient records.

4.8 Work on the proposed Codes of Practice was at a preliminary stage and it was intended that draft documents would be circulated to the members of the Advisory Group in the New Year. The Advisory Group was content to contribute to the development of the Codes through correspondence.

Previous Applications for Section 60 Support

4.9 The Advisory Group considered additional information that had been submitted in support of applications that had been discussed at previous meetings, as follows:

(i) Research to develop a methodology for the identification of patients in primary care with a diagnosis of cancer

At its previous meeting, the Advisory Group had considered an application from Shane Pascoe for research to develop a methodology for the identification of patients in primary care with a diagnosis of cancer [ref PIAG 3-09(i)/2003]. The application had been approved by the Advisory Group subject to the applicant providing an adequate system level security policy. The Advisory Group agreed that the policy document that had since been submitted met its requirements. It therefore formally approved the application.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval;
(ii) The register of activities carried out with Section 60 support to be updated to include details from the application.

(ii) Dr Amanda Daley, The Centre for Sport and Exercise Science, Sheffield Hallam

At its March meeting, the Advisory Group had considered an application from Dr Amanda Daley (ref PIAG 1-08(d)/2003) for support to obtain patient identifiable information without consent for use in a research study to investigate the effects of exercise therapy in women who had had breast cancer. She sought access to patient contact details so that their treating oncologist or surgeon could seek their consent to be included in the study. The application was approved by the Advisory Group subject to the applicant providing an adequate system level security policy. The Advisory Group agreed that the policy document that had since been submitted met its requirements. It therefore formally approved the application.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval;
(ii) The register of activities carried out with Section 60 support to be updated to include details from the application.

(iii) EPIC-Oxford Study

At its previous meeting, the Advisory Group had considered an application from Dr Timothy Key for the European Prospective Investigation into Cancer and Nutrition Oxford Cohort (EPIC-Oxford) [ref PIAG 3-09(e)/2003]. The application had been approved subject to Dr Key confirming that he would: act as information custodian for the study; provide a written explanation of how his study would comply with the principles of the Data Protection Act; implement an appropriate data archiving and destruction policy.

The Advisory Group agreed that Dr Keys' had responded appropriately and therefore formally approved the application.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval;
(ii) The register of activities carried out with Section 60 support to be updated to include details from the application.

(iv) Study to identify and map new genes predisposing to breast and colon or breast and thyroid cancer

At its previous meeting the Advisory Group had considered an application from Professor Shirley Hodgson for a study to identify and map new genes predisposing to breast and colon or breast and thyroid cancer [ref PIAG 3-09(j)/2003]. The Advisory Group had agreed that it could not approve the application until additional information had been submitted as follows:

- That the applicant explained in more detail how they would comply with each of the 8 principles of the Data Protection Act;
- That a system level IT security policy be submitted;
- That an explanation of how long the applicant intended to retain patient identifiable information be provided;
- That an appropriate data destruction policy be implemented;
- That the applicant explained their corporate IT arrangements (a corporate NHS IT policy had been submitted but the application stated that they were connected to JANET – a university network).

The Advisory Group considered Professor Hodgson's response and agreed to approve her application subject to: provision of a system level security policy; and a written commitment to a more effective data destruction policy.

ACTION: Secretariat to obtain additional information.

(v) Professor Jeremy Coid, Forensic Psychiatry Research Unit, St Bartholomew's Hospital

At its March meeting the Advisory Group had considered an application from Professor Jeremy Coid (ref PIAG 1-08(h)/2003) for support to obtain patient identifiable information without consent for a research study into the costs of

admission to medium secure psychiatric services and to a range of outcomes following discharge. The application explained that the study covered more than 1,600 patients, many of whom would have been lost to contact and some of who would be unable to understand documentation. It was agreed that before the Advisory Group could consider whether or not to approve the application, additional information was required as follows:

- substantive evidence to support Professor Coid's claim that obtaining consent was impracticable
- a copy of the latest version of the data security policy for Queen Mary College
- clarification about whether the LAN network the study's laptop will be connected to is controlled by the University or NHS department
- further information about how Professor Coid intended to destroy data held electronically

The Advisory Group agreed that Professor Coid had responded appropriately and that the application should be formally approved.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval;
(ii) The register of activities carried out with Section 60 support to be updated to include details from the application.

5. Government Green Paper, "Every Child Matters"

5.1 The Advisory Group had previously considered the Government Green Paper, "Every child matters" and submitted comments to the Secretariat. A draft response to the consultation on the Green Paper [PIAG 4-04/2003] had been prepared for discussion.

5.2 The Advisory Group agreed a number of minor changes to the text. In addition, it agreed that the following issues should be emphasised in its response:

- Evidence from the General Household Survey that young children had regular contact with the NHS, but rarely had contact with Social Services or other non-health organisations;
- That health data should be held separately from education and social service records;
- That mechanisms should be established to ensure that flags on children's records were checked for accuracy, or were removed when concerns were no longer justified;
- That information should be made available to parents informing them of access rights and the process for checking accuracy;

ACTION: Secretariat to amend the Advisory Group's response to the consultation and to submit revised version to the DfES.

6. NHS Care Records Service

6.1 The Advisory Group considered an extract from the Output Based Specification for the NHS Care Records on Information Governance (PIAG 4-05(a)/2003) and a presentation by Ms Marlene Winfield, Head of Public Engagement for the National Programme for IT.

6.2 Ms Winfield described the research she had carried out into public attitudes to the National Programme for IT (NPfIT) in the NHS, and how the NPfIT had responded.

6.3 Ms Winfield described how the NHS Care Records Service would work: every patient would have an electronic record that could be shared in a pseudonymised form. The "spine" of the record would include demographic information about the patient, information about allergies, medication, current conditions, treatment preferences and a summary medical record. The records would also include a sealed envelope – a facility that would enable patients to restrict access to information about certain health events; however patients would be unable to use this facility during the first year of the care records service.

6.4 Ms Winfield confirmed that any patient receiving NHS treatment would be required to have an electronic health care record containing identifiable information. Patients' opt-out rights would be restricted to preventing identifiable information from being shared.

6.5 The Advisory Group believed that the proposals could undermine patient confidentiality. It had discussed this issue with Dr Anthony Nowlan from the NHS Design Authority at its training day in June 2003 and had suggested that the spine of the electronic health record should contain demographic data only. It was the Advisory Group's view that the summary medical record or accumulated record of events should be held separately so that information that patients regarded as sensitive could not be seen by everyone who had access to the electronic care records system.

6.6 The Advisory Group was very concerned that its concerns had not been addressed. It believed that patients should be informed of the content of their electronic health record and have the right to object to some information from being included. This would be particularly important in the first year when the sealed envelope facility was unavailable. The Advisory Group sought assurance that steps would be taken to address these concerns, and that it would be kept better informed of developments in the future so that it could ensure its views were taken into account.

6.7 The Advisory Group also sought reassurance that the proposals had a secure basis in law.

ACTIONS: **(i) Secretariat and Ms Winfield to provide additional information to the Advisory Group on legal and other issues in relations to the NHS Care Records Service.**
(ii) Secretariat to develop proposals to ensure the Advisory Group was effectively consulted one development within the National Programme.
(iii) Ms Winfield to provide update at next meeting.

7. The Confidential Enquiries

7.1 The Advisory Group considered a submission from the National Institute for Clinical Excellence and applications for Section 60 support from each of the Confidential Enquiries (PIAG 4-08(a-d)/2003).

7.2 The Advisory Group agreed that NICE had not adequately addressed the consent issue in its submission, and had failed to recognise that different activities carried out by the Confidential Enquiries could adopt different approaches to obtaining consent. While it might be practicable to obtain consent from patients for research studies with small cohorts, other options might be more appropriate for larger studies. Members of the Advisory Group also noted that patients were required to sign a number of consent forms before they received treatment so it might be possible at that time to obtain consent for data to be supplied to the Confidential Enquiries.

7.3 The Advisory Group was concerned that the Confidential Enquiries claimed that it would be difficult to make progress towards using pseudonymised data because some NHS organisations failed to strip identifiers from data they sent to the Enquiries, and because some parts of the NHS did not use the NHS number as a unique identifier for patients.

7.4 The Advisory Group also believed that NICE and the Confidential Enquiries needed to do more to involve patients and health service users in their work.

7.5 Members agreed to approve the applications for support under Section 60 of the Health and Social Care Act 2001 for the Confidential Enquiry into Peri Operative Deaths (CEPOD), the Confidential Enquiry into Maternal and Child Health (CEMACH) and the Confidential Inquiry into Suicides and Homicides (CISH), subject to the following conditions:

(i) That NICE report back within 12 months on the implications for the Confidential Enquiries of any guidance issued to the NHS following the consultation on Making Amends

(ii) That NICE report back within 6 months on why the NHS number cannot be used as a unique identifier, and specifically
- How is its use was limited (i.e. who does not use it, and how many patient records obtained by the Confidential Enquiries do not have NHS number)
- When organisations that supply data to the Confidential Enquiries, but did not use NHS number, were likely to adopt systems using the NHS number.

(iii) That NICE provide an update within 6 months on progress to develop patient information materials, with an expectation that leaflets would be distributed in 12 months time

(iv) That the working group on consent NICE had established with the Confidential Enquiries should broaden its remit to consider informed consent.

7.6 With regard to each of the Confidential Enquiries, the Advisory Group required the following actions to be taken:

(i) Each of the Confidential Enquiries to provide within 12 months a project plan – with implementation dates – of how they planned to take advantage of anonymisation technologies made available to the NHS through NPfIT

(ii) Each of the Confidential Enquiries to demonstrate within 12 months that they had taken steps to encourage active involvement by lay/patient representatives, including integration of lay involvement into a wider range of activities.

(iii) NCEPOD to provide conformation of improvements it had implemented since a risk assessment undertaken in October 2002.

(iv) NCEPOD to explain whether or not its systems supported remote use of patient information (i.e. though internet access).

(v) CEMACH to provide information on the outcome of a risk assessment undertaken in November 2003 and to explain what, if any, actions had arisen.

(vi) NCISH to explain how it would partition and control the separate data processing and security/confidentiality arrangements for each of the activities carried out with Section 60 support.

(vii) NCISH to provide a further update to its IS&M audit progress report with an indication of when it planned to undertake its next review.

ACTIONS: (i) Secretariat to inform NICE and the Confidential Enquiries of the Advisory Group's approval and the conditions applied to it; (ii) The register of activities carried out with Section 60 support to be updated to include details of the Confidential Enquiries.

8. Applications for Section 60 Support

8.1 The Advisory Group considered new applications for Section 60 support as follows:

(i) Application from the Oxford Register of Early Childhood Impairments

8.2 The Advisory Group considered an application for Section 60 support from the Oxford Register of Early Childhood Impairments (ORECI) [PIAG 4-09(b)/2003]. The application explained obtaining identifiable data with consent was impracticable because data on children with multiple impairments was collected from multiple contacts with the NHS; and because there was difficulty in diagnosing cerebral palsy (can take up to 5 years) – the applicant wished to avoid upsetting parents unnecessarily.

8.3 The Advisory Group noted that the Register was in the process of developing a 3-step consent process: anonymised Rapid Report notification of a case which after assessment would lead to consent being sought from parents; development of information materials and consent forms for obtaining consent at diagnosis; development of information materials in order to obtain consent from children when they were competent. These were developments welcomed by the Advisory Group, which agreed that families had a right to know about the Register and that ultimately data should be obtained with consent.

8.4 The application was approved subject to the following conditions being met by the applicant:

- That a system level security policy was provided and a risk assessment conducted for the Register;
- That information materials about the Register would be produced and distributed;
- That the Register implement its objectives on consent in a staged process over 24 months (Stage 1 within 12 months, Stages 2 and 3 within 24 months);
- That within 12 months the register develop a policy on data retention and destruction, with a view to removing identifiers from data as soon as practicable.

ACTION: Secretariat to obtain additional information from the applicant prior to approval being recorded on the register of activities carried out with Section 60 support.

(ii) Application from the Health & Safety Executive for Mesothelioma and Asbestosis Registers

8.5 The Advisory Group considered an application from the Health and Safety Executive for Section 60 support for its Mesothelioma and Asbestosis Registers [PIAG 4-09(c)/2003].

8.6 The Advisory Group noted that the registers had been used since the 1960s to provide statistics on the incidence of mesothelioma and asbestosis, and the application argued that it was impracticable to obtain consent from patients because it was insensitive to raise these issues with patients at the point of diagnosis, and because the HSE had no formal links with the NHS.

8.7 The application was approved subject to the HSE meeting the following conditions:

- Provision of a system level security policy;
- That greater user/patient involvement should be promoted in the development of HSE projects using patient information;
- That the HSE report in 12 months on the potential for using ICD10 data in place of identifiable data.

ACTION: Secretariat to obtain additional information from the applicant prior to approval being recorded on the register of activities carried out with Section 60 support.

(iii) Application from Health Solutions Wales for the National Community Child Health Dataset for Wales

8.8 The Advisory Group considered an application from Health Solution Wales for Section 60 support to establish a National Community Child Health Dataset for Wales [PIAG 4-09(d)/2003]. The applicant proposed to use the dataset to support a wide range of activities including supporting the clinical management of sick children, performance management of NHS children's services in Wales, monitoring the

development of all children up to the age of 5, and to develop, monitor and evaluate government policies.

8.9 The Advisory Group was concerned that the application was too wide-ranging. Although the proposed dataset would support a number of important initiatives, there was little evidence of patient/user involvement in the development of your proposals. Members agreed that that it was important that this work should be undertaken by engaging with parents and that you should seek "buy-in" from the wider population.

8.10 The Advisory Group agreed that the application should not be approved. It recommended that where the dataset would be used to support operational activities then identifiable data should be processed with informed consent. However, where the dataset would be used for other purposes then pseudonymised/anonymised data should be processed.

ACTION: Secretariat to inform the applicant of the Advisory Group's decision.

(iv) Application from the National Cancer Analysis Team for an intercomparison of data collected by ONS on cancer registration

8.11 The Advisory Group considered an application from the National Cancer Analysis Team for Section 60 support to process patient identifiable data in order to undertake an intercomparison of data collected by the Office for National Statistics on cancer registration [PIAG 4-09(e)/2003].

8.12 Section 60 support was required because the applicant had no way of contacting patients to obtain their consent to use the required data, and identifiable data items (NHS number and full postcode) were required for linkage and geographical analysis. It was intended that the applicant would link data already obtained with Section 60 support with ONS data on cancer registration.

8.13 The Advisory Group approved the application, subject to steps being taken by the National Cancer Analysis Team to institute a new risk assessment.

ACTIONS: (i) Secretariat to inform the National Cancer Analysis Team that its application had been approved;
(ii) The register of activities carried out with Section 60 support to be updated to include details of the application.

(v) Application from Dr G W Odell (Guy's, King's and St Thomas' Dental Institute) for a "Ploidy" analysis study

8.14 The Advisory Group considered an application from Dr G W Odell to process patient identifiable information for a "ploidy" analysis study [PIAG 4-09(f)/2003].

8.15 Identifiable data was required for linkage, audit and geographical analysis in order to test the effectiveness of image based ploidy analysis to predict the development of mouth, prostate and ovarian cancers. The applicant claimed that it was impracticable to obtain consent from approximately 5,000 patients treated since

1990 many of whom were elderly, unwell from high tobacco and alcohol use, or who may have died or moved away.

8.16 The Advisory Group approved the application, subject to the following conditions:

- That additional information be provided in order to demonstrate that an appropriate Information Custodian had been appointed for the study;
- That the applicant supply a detailed explanation of how the study will comply with each of the 8 principles of the Data Protection Act.

ACTION: Secretariat to obtain additional information from the applicant prior to approval being recorded on the register of activities carried out with Section 60 support.

(vi) Application from Dr Brian Cottier for support for an analysis of existing data sources to demonstrate variation in coronary heart disease service provision in England

8.17 The Advisory Group considered an application from Dr Brian Cottier of the National Cancer Analysis Team for Section 60 support to process patient identifiable data for an analysis to demonstrate variation in the provision of CHD services across England [PIAG 4-09(g)/2003].

8.18 The applicant required NHS number and full postcode in order to carry out the proposed data analysis, for linkage and geographical analyses.

8.19 The Advisory Group agreed that the identifiable data required by the applicant had been kept to the minimum amount that was practicable and approved the application. However, it was suggested that the applicant should undertake a new risk assessment in relation to IT security as it was 3 years since they had last so done.

ACTIONS: (i) Secretariat to inform the National Cancer Analysis Team that its application had been approved;
(ii) The register of activities carried out with Section 60 support to be updated to include details of the application.

(vii) Application from Dr Jane Armitage (University of Oxford) for a study of cardiovascular events in diabetes (the "ASCEND" study)

8.20 The Advisory Group considered an application from Dr Jane Armitage for Section 60 support to process patient identifiable information for a study of cardiovascular events in diabetes [PIAG 4-09(h)/2003].

8.21 The applicant sought access to patient identifiable data in order that an appropriate cohort could be identified and then patients could be contacted and invited to participate in the study.

8.22 The Advisory Group approved the application, subject to the following conditions:

- That the applicant confirm that initial contact with patients to obtain their consent will be via a clinician know to them (e.g. their GP or the consultant responsible for their care)
- That the applicant clarify what was meant by the "regulatory authorities" referred to in their consent form, and confirm that this form was approved by an appropriate research ethics committee
- That the applicant clarify their BS7799 status or advise when compliance was expected
- That the applicant provide a system level security policy and confirm when their corporate IT security policy was implemented
- That the applicant provide further information about their risk assessment – when was it undertaken, what did it recommend and when were the recommendations implemented.

ACTION: Secretariat to obtain additional information from the applicant prior to approval being recorded on the register of activities carried out with Section 60 support.

(viii) Application from Dorset RDSU for a quantitative and qualitative evaluation of intermediate care of the elderly

8.23 The Advisory Group considered an application from Dorset RDSU for Section 60 support to process patient identifiable information for an evaluation of intermediate care of the elderly PIAG 4-09(i)/2003].

The Advisory Group felt unable to approve the Execution of NAL Explorer

8.24 application at the current time. It was particularly concerned that the reasons supplied for not being able to obtain informed consent from patients were fairly weak, since it was not sufficient to assert that "the numbers will be too large to make obtaining consent from each patient practical".

ACTION: Secretariat to obtain additional information from the applicant prior to approval being recorded on the register of activities carried out with Section 60 support.

(ix) Application from Dr Rory O'Conor (British Burns Association) to undertake a strategic analysis of the incidence and geography of burns in England for the purpose of planning future services

8.25 The Advisory Group considered an application from Dr Rory O'Conor to undertake a strategic analysis of the incidence and geography of burns in England [PIAG 4-09(j)/2003].

8.26 The Advisory Group noted that Dr O'Conor had gone to significant lengths to reduce the amount of identifiable data he required to an absolute minimum. Although he still required access to full postcode, it was intended that this data would be removed from his database when it had been geocoded.

8.27 The application was approved, subject to the following conditions:

- That the applicant clarify the relationship between his NHS trust and the British Burns Association
- That the applicant provide a system level security policy and confirm the implementation date of his corporate IT security policy.

ACTION: Secretariat to obtain additional information from the applicant prior to approval being recorded on the register of activities carried out with Section 60 support.

(x) Application from Professor Jenny Donovan (Department of Social Medicine, University of Bristol) for study to evaluate the effectiveness and cost-effectiveness of population based screening for prostate cancer

8.28 The Advisory Group considered an application for Section 60 support to process patient identifiable information for a study to evaluate the effectiveness of population based screening for prostate cancer [PIAG 4-09(k)/2003].

8.29 Patient identifiable data was required for the comparison arm of a study in order to flag patient records on the NHSCR. The applicant was concerned that a requirement to obtain informed consent may lead to more than 50% of patients failing to participate thereby undermining comparisons between the comparative and intervention arms of the study.

8.30 The Advisory Group approved the application subject to the following conditions:

- That the applicant confirmed they would not include in the comparison arm of the study data about patients who opted out of the intervention arm;
- That the applicant conduct a formal risk assessment to inform the design of IT systems in advance of data collection, and provide information about the outcome of the assessment and any resulting actions required;
- That the applicant provide a system level IT security policy and commit to implementing it before data collection;
- That the applicant provide details of how they meet each of the 8 principles of the Data Protection Act.

ACTION: Secretariat to obtain additional information from the applicant prior to approval being recorded on the register of activities carried out with Section 60 support.

(xi) Application from the Confidential Inquiry into Suicides and Homicides for a national study of prison suicides [PIAG 4-09(l)/2003]

8.31 The Advisory Group considered 2 applications from the Confidential Inquiry into Suicides and Homicides for Section 60 support for a study of prison suicides [PIAG 4-09(l)/2003], and a study of suicides among recently released prisoners [PIAG 4-09(m)/2003].

8.32 The Advisory Group agreed that the proposed studies were very important but it was concerned that Section 60 could not be used to allow access to prison health records, as it was uncertain whether or not the NHS was responsible this data. It therefore asked that the applicants provide additional information and, if necessary, legal advice about who was responsible for the management of prison health data.

8.33 In addition, the applicant was required to provide system level security policies for each study, and explain the arrangements for ensuring effective partition and separate processing of the data obtained for each study.

ACTION: Secretariat to obtain additional information from the applicant for consideration at the next meeting.

9. Any Other Business

9.1 There was no other business.

10. Date of Next Meeting

To note: Future meetings of the Advisory Group have been scheduled as follows:

- Tuesday 2 March 2004
- Monday 7 June 2004
- Monday 13 September 2004
- Monday 6 December 2004

(N.B. Members are also requested to hold Tuesday 7 December 2004 for a possible training day)