PATIENT INFORMATION ADVISORY GROUP

Meeting on Monday 5 December 2005 at 10.30am

Minutes

1. Present

Members: Professor Joan Higgins (Chair), Professor Mike Catchpole, Dr Tricia Cresswell, Dr Fiona Douglas, Ms Stephanie Ellis, Mr Michael Hake, Ms Ros Levenson, Ms Barbara Meredith, Professor Roy McClelland, Professor Sir Denis Pereira-Gray, Dr Peter Rutherford, Dr Michael Wilks.

In attendance: Mr Patrick Coyle, Ms Melanie Kingston, Mr Sean Kirwan Ms Karen Thomson and Mr Phil Walker.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on the 7 June 2005 were agreed to be an accurate record subject to a few minor amendments.

3. Matters Arising/Action Points:

3.1 The Chair reported that Ms Julia Palca had resigned. The Advisory Group therefore has two vacancies following the previous resignation of Dr Peter Furness. Contact was made with the NHS Appointments Commission with a view to giving directions to fill these vacancies. The Chair reported that in light of the Information Governance Review undertaken by Mr Harry Cayton, she proposed to defer filling these vacancies until the outcome of the review was known as it may mean a changed role for PIAG and require different areas of expertise to be included within the composition of the group. It was noted that the IG review had been considered by the NHS CfH Programme Board and would be considered by the DH Management Board within the next few weeks and published in the New Year.

3.2 It was noted that the points of action from the last meeting had been completed. A re-submission from the Northwest Institute for Bio-Health Informatics with respect to the Cardiac Rehabilitation Clinical Management System was still awaited.

4. Secretariat Report

4.1 The Secretariat report was received and its contents noted.

4.2 <u>Streamlining of application process with COREC</u>

The Advisory Group welcomed the agreement with COREC for the PIAG form to be integrated with the COREC application form. Ms Ellis and Dr Douglas undertook to work with the Secretariat on the revisions to the form.

Action – Dr Douglas & Ms Ellis to be consulted by Secretariat on a revised PIAG form.

4.3 NCEPOD Annual Review

Members welcomed the annual review report and the positive news about the increasing use and availability of the NHS number even in Emergency Care situations. The issues in relation to the use of the NHS number by the private sector were noted. The Advisory Group was content to approve the annual review.

4.4 BPSU Scleroderma study

The Advisory Group received the application for the BPSU study and was content with it in principle, subject to the clarification sought by the Secretariat and confirmation of appropriate security arrangements.

4.5 Long term care programme

The Secretariat updated members on the issues related to the Long-term conditions programme raised at the previous meeting. Members noted the advice that had been issued to PCTs. Concern was expressed by members that the standard referral process was not being followed, namely that referral should only occur once a treating clinician has discussed the options for care with the patient and obtained their consent for referral. The programme was proposing to use opt out. Members did not feel that this was appropriate. Whilst this relates to the delivery of care, it also pertains to how information flows and therefore rightly falls within the remit of the group.

4.6 Following discussion the Group agreed that the issues involved in this type of activity would become more significant, particularly because of the increasing use of the independent sector to deliver services. In light of this, it was agreed to discuss this in more detail at the next meeting and that the outcome of the discussions should be sent to the Chief Medical Officer for his consideration.

Action – Secretariat to revise the advice and to include this as an item on the next agenda.

5. Chair's Report

5.1 AMS report on the use of patient information in research

The Chair updated the group on the draft report from the Academy of Medical Sciences on the use of patient information in research, which would be published within a few weeks. In addition, she reported on her meeting with Professor Bob Souhami to discuss the contents of the draft report and its recommendations. The Chair expressed her thanks to Professor Souhami and the AMS for extending the courtesy of allowing her sight of the draft report. There were however a number of concerns with the report, specifically that it was factually inaccurate in several areas. AMS felt that, although PIAG was clearly committed to the promotion of high quality research, some of the Group's publications emphasised the regulation of research and patient confidentiality rather than the facilitation of research. Nevertheless, it was

acknowledged, in the draft report, that the PIAG secretariat did provide good advice to researchers seeking Section 60 support and that the Group had developed a great deal of expertise in handling issues of consent and confidentiality. The draft report recommended that PIAG should continue its work, as it provided essential legal support for important research. The Group discussed whether it could do more to publicise the work of PIAG, especially in the research community, and whether it could improve the transparency of its decision-making. Ms Meredith suggested that it might be helpful if PIAG were to develop a checklist for assessing Section 60 application. This would be based upon the criteria identified in the application form and would form the basis for systematic feedback to applicants. She offered to develop a first draft.

Additionally, it was agreed, as part of this, to consider what might be the benefits and disadvantages of meeting in public to discuss Section 60 applications, so that researchers and other stakeholders could observe the Group at work. PIAG members already take part in conferences and similar activities but could consider doing more to publicise the role of PIAG. The seminar, which is to be held in February 2006 for key stakeholders, should go some way towards raising the profile of the Group's work.

Actions: Chair & Secretariat to prepare response to AMS report
Ms Meredith to develop a first draft of a checklist for assessing applications
Chair & Secretariat to prepare a report for the Group on the benefits and disadvantages of meeting in public and further public & stakeholder engagement.

5.2 Other reports

The Chair brought to the Group's attention a new report published by the Council for Science and Technology called Better use of personal information. It promoted data-sharing but also discussed appropriate safeguards and suggested a way forward might be through the concept of citizens 'owning' their data. Additionally a report by the Cabinet Office had just been issued entitled Transformational Government, which was again about data sharing across government. The Chair also drew the Group's attention to the Chancellor of the Exchequer's Mansion House speech, which had included reference to increased investment in medical research by the Bio-medical industry and investment in NHS IT to support this whilst also protecting patient confidentiality.

6. Applications previously considered

6.1 University of Birmingham - PSA & prostate cancer linkage study (3-07(1)/2005

The Advisory Group considered this re-submission for Section 60 support. The Advisory Group accepted that consent would not be viable and were pleased with the approach that had been taken to ensure that identifiable information was held for the minimum time necessary and that identifiers would be held separately from clinical data. Members felt, however, that there were still outstanding issues with the

application. The Advisory Group approved the study in principle, provided the applicant met the following conditions:

- Provided confirmation of what clinical data is required and that is limited to that relevant to prostate cancer diagnosis and PSA testing.
- That a System Level Security policy would be submitted and that appropriate measures are in place to ensure that data would be transferred securely.
- The Advisory Group was disappointed with the response on user involvement and proposed that the researchers be requested to consider involving prostate cancer user groups. Members also felt that a patient information leaflet should be developed with the advice of the Secretariat, which could be disseminated through such groups.

ACTION: Secretariat to inform the applicants of the Group's decision and obtain confirmation of approval from Prof Catchpole / Dr Cresswell subject to the response to the above conditions.

6.2 University of Leeds – Health facilitation and Learning disability: Evaluating the role of health Facilitators (3-07k)/2005)

The Advisory Group considered a re-submission from the University of Leeds for this study and agreed that the applicant had addressed the issues previously raised. The Advisory Group was concerned by the use of the term 'register' as in other respects this appeared to be a cohort study. The Advisory Group approved the application subject to clarification that it was not intended to establish an ongoing register and that identifiers would be removed as soon as possible.

The Advisory Group also had concerns about the quality of the research and asked the Secretariat to raise this as an issue with Carol Lupton.

ACTION: Secretariat to inform the applicants of the Group's decision and to contact Carol Lupton.

6.3 UCL – Prognosis of CHD in different South Asian Populations (3-07(g)/2005)

The Advisory Group considered this re-submission for Section 60 support. The Advisory Group were dissatisfied still with the response of the applicant. In particular, the comments on user involvement had not been taken seriously and sections (o) and (p) remained weak. The Advisory Group did not approve the application. If the Applicant were to re-submit again, the Advisory Group would require user involvement to be strengthened and would want to see that appropriate information leaflets had been prepared for use by the relevant clinics in these hospitals. Data destruction methods would also need to be clarified.

ACTION: Secretariat to inform the applicants of the Group's decision

6.4 Mental Health Act Commission – Count me in – National Mental Health and Ethnicity Census (1-08(b)/2005)

The Mental Health Act Commission had written to the Secretariat to request if they could repeat the census previously approved in March and included the changes they wished to make. Members felt that if the Group had wanted to do a straightforward repeat of the previous census a letter would have been sufficient. However, given that the applicant was proposing to make substantive changes the Group agreed that a full new application was necessary in order to explain and justify the changes to the data items requested. This explanation should relate not only to the proposed changes to identifiers requested but also because of the sensitivity of some of the additional data items. In particular, the group was concerned about including sexual orientation. Dr Rutherford reported that there was a new initiative in relation to asking for and recording sexual orientation, which had come from the Equal Opportunities Commission. The secretariat, was asked to clarify this. The Group additionally commented that they would like to see user involvement further strengthened.

ACTION: Secretariat to inform the applicants of the Group's decision

6.5 Institute of Cancer Research – Study into occupation and mesothelioma (1-08(e)/2003)

The Advisory Group considered this re-submission for a study that had been previously approved, but where the data had not been collected. The re-submission had sought to address the conditions of approval previously placed on the applicant, specifically that the first point of contact in seeking consent was through a treating clinician and that appropriate data destruction had been put in place. The Advisory Group approved the application but asked that user group involvement be strengthened.

ACTION: Secretariat to inform the applicants of the Group's decision

7. Applications for Section 60 support

7.1 National Joint Register [4-05(b)/2005]

The Advisory Group considered an application from the National Joint Register (NJR) for support under Section 60 to allow record linkage and data analysis where patient consent had not been sought. Professor Catchpole declared that although not directly involved with the NJR, he did have contact with Momenta and AEA Technology through his work for the DH Sexual health dataset group.

The Advisory Group acknowledged that the quality of the application was excellent and that the Registry was pursuing best practice in terms of both seeking patient consent and involving users in its decision-making.

Members were very concerned that the important work of the registry and potentially the quality of patient care was being compromised because of poor practice by some Trusts to inform patients appropriately and seeking their consent for inclusion on the Register and consequently not participating fully in the Register. Members were concerned that providing Section 60 support should not be seen by those Trusts as a disincentive to seeking patient consent. The Advisory Group agreed that the evidence provided by the Register on consent rates across different Trusts should be brought to

the attention of Sir Nigel Crisp and the Royal College of Surgeons of England. The Chair was asked to write on behalf of the Group.

Action – Chair to write to Sir Nigel Crisp and the Royal College of Surgeons.

The Advisory Group agreed to approve the Register with the following conditions:

- That consent would still be required, however when consent had not been sought or it was unknown whether consent has been sought then Section 60 support may be utilised to obtain identifiable information. Particular care needs to be taken to ensure that dissent is still respected and no identifiers submitted.
- Where Section 60 has been utilised, once the NHS number has been traced or validated through NSTS, name and address should be removed and postcode and date of birth should be reduced. Consideration should be given, to only using name and address where an NHS number, postcode and date of birth are not available or prove to be invalid.
- That the Registry demonstrates year on year improvement in consent rates in its annual review.
- That consideration would be given to maintaining valid consent and appropriate data destruction (de-identification of data) over the longer term.
- That a System Level Security Policy is submitted setting out the security considerations and that the relationships and accountabilities are clarified in relation to security management.
- That the Secretariat be informed of new linkage arrangements such as with HES or PEDW.

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

7.2 North West London SHA - Maternity Services Modernisation Project – Booking register [PIAG 4-05(c)/2005]

The Advisory Group considered an application from the North West London Strategic Health Authority. The Advisory Group agreed that this was not an appropriate use of Section 60 and that what was required was for Trusts to improve their administration systems.

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

7.3 Office for National Statistics – Access to birth notification information for statistical purposes [PIAG 4-05(d)/2005]

The Advisory Group considered an application from the ONS for access to birth notification data for the purposes of statistical analyses. This would include birth weight and gestational age data. It was noted that this was similar to an application from a City University collaboration to capture gestational age data. It was agreed that this was important work to inform the DH on risk factors affecting the health of infants. The Advisory Group agreed to approve the application subject to the following conditions:

- Improved user involvement and a timeline for the development of appropriate information materials for parents.
- Satisfactory security review arrangements are put in place if not already in place and findings reported to PIAG.
- That confidentiality clauses are included in staff contracts and enforceable through disciplinary procedures as the Official Secrets Act is not applicable to health data
- That this data is held in England or Wales in order to be covered by Section 60.

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

7.4 Department of Primary Care and General Practice, University of Birmingham – Variation in NHS utilisation of vault smear tests in women post-hysterectomy. [PIAG 4-05(e)/2005]

The Advisory Group considered an application for a retrospective study into the variation in use of vault smear tests in women post-hysterectomy in the West Midlands 2003-5. Members felt that in some respects this might be considered integral to quality assuring the care given as part of the cervical screening programme. Following discussion the Advisory Group agreed that they were content to approve the activity but had serious reservations about approving the application. The reservations were concerned with a lack of understanding, on the part of the applicant, with respect to patient perspectives, in particular with regard to the need for consent, as demonstrated by the insensitivity of some of the language. Ms Meredith, Ms Levenson and Ms Ellis offered to compile comments on the application for the applicant in order to begin to address this. This suggestion was supported by other members.

The Advisory Group therefore agreed to approve this activity subject to the following conditions:

- That the applicant undertakes to learn about patient perspectives and the need for consent to provide a review of her application in light of this in six months.
- That the applicant undertakes further user involvement
- That Caldicott Guardian support is obtained
- That appropriate patient information materials, including an opt-out mechanism, are developed.
- That appropriate security measures are put in place.

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

7.5 Vascular Society of Great Britain and Ireland – National Vascular Database [PIAG 4-05(f)/2005]

The Advisory Group considered an application from the Vascular Society of Great Britain and Ireland to establish a national registry of mortality and outcomes for four major procedures.

Section 60 support was needed, as both NHS number and full date of birth were required to enable record linkage and validation from multiple reporting sources. The Advisory Group had no desire to prevent work in this area or stop the collection of data, however members felt that the applicant should consider the approach used for audit by Cardio-thoracic surgeons, i.e. that consent was obtained prospectively to see if an application for Section 60 support was in fact required.

The Advisory Group agreed therefore to refer this application while this work was being undertaken, and proposed that the applicant re-submit their application to the next meeting if this alternative was not appropriate.

Other comments, which the applicant should consider for re-submission, are:

- Developing a more permanent exit strategy.
- That the applicants produce an appropriate patient information leaflet, which includes a mechanism for opting out.
- That the applicants improve their user involvement

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

This application raised the issue of appropriate ways of obtaining consent alongside other consent processes such as consent to treatment. It was suggested that this should be considered as part of the Away day's agenda in March.

8. UK Biobank

8.1 The Advisory Group considered an application for Section 60 support from the UK Biobank. The Advisory Group very much recognised the special significance and possibly unique importance of the Biobank in research terms. During a lengthy and considered discussion a number of key points emerged which have been outlined below. The Advisory Group devised a strategy for how this work might be undertaken without disclosure of information to UK Biobank prior to patient consent being obtained. It was noted that the Minister of state had taken an interest in this issue and that she or the Secretary of State may wish to make this decision. In light of this, it was agreed to defer a decision by the Advisory Group until it had been agreed with the minister how this issue was to be managed. The Group asked Mr Walker to present the Advisory Group's views and raise this issue with the minister in the first instance and the Chair expressed her willingness to meet with the minister to discuss the issue further. It was agreed that should it be decided that the Advisory Group should take this decision; this would probably require an additional meeting prior to the next scheduled meeting.

8.2 It was noted that in terms of the letter of the law, demographic information such as name address and age would not be considered confidential. Nevertheless, despite the legal position, the reality and perception of most patients would be that the PCTs or other agencies of the NHS only know patients' ages and addresses because they have given this information to their doctor or nurse in their general practices, in what most patients would see as a confidential medical consultation. Furthermore, patients expect that no personal information would be disclosed to third parties

without consent or for statutory purposes. Members therefore had reservations, about Biobank's proposals both to approach patients directly and to act as an agent for the NHS in managing the mailing and recruitment process. A letter sent directly by Biobank to half a million patients would create the perception of general practices and the NHS handing over personal data to a third party without consent and could have a detrimental effect on the relationship of trust between patients and their clinicians.

8.3 After much discussion, the Advisory Group agreed to propose that the Department of Health/NHS could write directly to the patients in the age bands sought by Biobank. There would be then no possible breach of confidentiality, as patients would understand that they are registered with the NHS. This approach would protect the reputation of Ministers, of the doctors and nurses in the general practices, and of NHS managers. This letter could enclose information materials from Biobank, explaining its purpose and why this research is important.

8.4 Giving patients information and then allowing them to choose, is not only good practice but also a good model of empowering patients. Patients would be treated as adults, fully informed, and could choose for themselves. Another advantage of this process would be that the Department could give formal support to Biobank and encourage patients to take part, which should improve the response rate.

8.5 It was noted that there was a lack of clarity in the documents provided by Biobank, about how many patients would be required as reference was made to a pilot having a 50% response rate, whereas, elsewhere it was suggested that an approach to as many as five million patients may be necessary to obtain 500, 000 acceptances. Biobank needs a sample, which properly includes the right balance of men and women, of ages, and of socioeconomic categories. The Advisory Group acknowledged that the proper balancing of the sample would be crucial to the validity of research results based on Biobank data.

8.6 There were in essence, two ways of getting the sample. Biobank have proposed doing the sampling from the full list of all the names and addresses that they hope to receive from the NHS. They then propose to send out actual appointments to the extent of about ten times the number of people they need, and then work out their sample from the people who accept the appointment.

8.7 The alternative approach proposed by the Advisory Group, would be for the NHS to approach people by letter, enclosing Biobank's information material, and asking them to reply direct to Biobank through a form indicating their age, sex, and postal address, and any other information Biobank needs. Biobank would then draw their samples from those replies. This system has some advantages, as some people may be irritated to be sent an appointment prior to having given consent and from an organisation that they have never heard of before. Additionally far fewer appointments would then be needed, as other research, as reported by Dr Cresswell, shows that once people have indicated interest, they are very much more likely to give consent to participate.

8.8 Members expressed their willingness to engage in further dialogue with Biobank staff and to work with them on the template letters and information materials.

9. Childhood obesity surveillance

9.1 Because of the time taken discussing the UK Biobank, the Advisory Group agreed to deal with the childhood obesity surveillance project by email. Dr Cresswell was asked by members to draft a response, which members would then have an opportunity to comment upon, prior to approval by Chair's action. Members did however agree that it would be inappropriate for health data to be held on a DFES database.

Action – Dr Cresswell to draft response on behalf of the Advisory Group. Secretariat to circulate for comment and then approval by Chair's action.

10. Counter Fraud and Security Management Services

10.1 Again because of time constraints, members were asked to comment on the documents by email. The Secretariat would then draft a response and circulate for comment and approval by members.

Action – All members to comment on the briefing documents provided. Secretariat to draft a response for circulation by email.

11. Care Record Development Board

11.1 The Chair undertook to circulate a note updating the Group about the work of the Care Record Development Board after the meeting.

Action – Chair to draft and circulate a note about the CRDB.

12. Any Other Business

12.1 Update on the Research and Development meeting held on 15 November.
Ms Ellis volunteered to circulate a brief note about this meeting by email. It was agreed that any further issues related to this or the above items, requiring discussion would be put on the next agenda.

Action – Ms Ellis to circulate a note about the meeting.

13. Future meetings for 2006

13.1 Monday 13 March 2006 – Away day
Tuesday 14 March 2006
Tuesday 13 June 2006
Monday 11 September 2006
Wednesday 13 December 2006