PATIENT INFORMATION ADVISORY GROUP

Meeting on Monday 6 June 2005 at 10.30am

Radisson Grafton Hotel
Tottenham Court Road, London

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, Dr Peter Rutherford, Dr Michael Wilks.

In attendance: Mr Patrick Coyle, Ms Karen Thomson, Mrs Anne Ward, Miss Victoria Lowther, Mr Jim Shannon.

2. Apologies

Apologies were received from Dr Roy McClelland, Ms Barbara Meredith, Ms Julia Palca, Professor Sir Denis Pereira Gray, and Professor Martin Severs.

3. Minutes of last meeting

The minutes of the previous meeting of the Advisory Group that had taken place on Tuesday 15 March 2005 [PIAG 2-02/2005] were agreed to be a true record.

4. Matters Arising/Action Points:

The Advisory Group considered the Secretariat Report and the following items were discussed:

4.1 Central Office of Research Ethics Committees (COREC) of the National Patient Safety Agency (NPSA)

The Chair reported that the PIAG Secretariat would be meeting with Janet Wisely, COREC Operations Director and colleagues at the NPSA to discuss several issues including how to streamline the application process for researchers to both PIAG and RECs. This meeting was due to take place in July and the Secretariat would report on it at the next meeting.

4.2 NHS Connecting for Health Public Information Campaign

The Chair reported that the letter drafted to Patricia Hewitt concerning PIAG's views on the Public Information Campaign had not been sent because progress on the aspects of concern to the Advisory Group had been made. As an alternative, Marlene Winfield, Head of Public Engagement for NHS Connecting for Health, was in attendance to update

the Advisory Group on the Public Information Campaign and the Care Record Guarantee and a summary report of the campaign was tabled.

The Advisory Group welcomed the fact that the campaign material would be available in a range of languages and formats. They were also interested to note that staff would receive communications about the programme five months before its launch and that patients would begin to be informed months before. The Chair suggested that the Secretariat organise to update the Group on the work of the Care Record Development Board and the Ethics Advisory Group for the next meeting.

ACTION: Secretariat to obtain an update for the next meeting.

4.3 Cancer Research UK – Extension to Prostate Cancer ProtecT treatment trial [now called the CAP study: Comparison Arm for the ProtecT treatment trial.] PIAG 3-06(e)/2004

The Advisory Group considered a response from Cancer Research UK regarding the CAP study following the Group's rejection of the application at the last meeting in March 2005. Cancer Research UK wished to appeal against the Advisory Group's decision and proposed that for men with incident prostate cancer in the comparison arm that they be allowed to use patients' information unless they chose to opt-out. The Advisory Group required further information on the proposed arrangements regarding consent and were happy for the Secretariat to act on the Chair's Action.

ACTION: For the Secretariat to obtain further information from Cancer Research UK and take Chair's action on the response received.

4.4 Code of Practice on Records Management

The Chair reported that the Department of Health was currently writing a draft Code of Practice on Records Management for the NHS. This Code of Practice, when finalised, would supersede current Department of Health guidance which is out of date. The Code is expected to be released for consultation at the end of July for 12 weeks. The Secretariat advised that they would contact members in order to collate a response from PIAG if this was felt to be appropriate.

ACTION: Secretariat to advise members when the consultation starts and provide a PIAG response.

4.5 Identity Cards Bill

The Chair reported that the Identity Cards Bill was reintroduced to Parliament on the 25 May following the election. The current Bill is similar to the previous Bill, with some minor amendments in relation to: extending the responsibilities of the National Identity Scheme Commissioner; changing the penalty for failing to surrender an ID card from criminal to civil; and requiring the provision of information from the Register without consent to be subject to

an affirmative resolution process. This is unlikely to have implications of interest to the Advisory Group as it has been agreed that health information will not be included on ID cards.

4.6 Cancer Bill

The Chair reported that the Advisory Group would be contacted in the near future for comments on the Cancer Bill. The Bill itself stipulates that patient information may be used for the purposes of registration and research and would obviate the need for section 60 support. Mr Phil Walker at the Department of Health had already provided initial comments but the Group would be expected to provide more detailed comments on the expected revised version. The Secretariat agreed to circulate the current version in the meantime.

ACTION: Secretariat to circulate current version of the Cancer Bill for initial comments.

4.7 Lord Warner's Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees.

The Chair informed members that the report from Lord Warner's Ad Hoc Advisory Committee would be published this week and would be circulated to members and put on the agenda for the next meeting if necessary.

ACTION: Secretariat to circulate the report to members when published.

4.8 Institute of Cancer Research – Investigation of referral rates in men with raised prostate specific antigen levels – Extension of Section 60 support [PIAG 3-06(f)/2004]

The Secretariat reported that this study into prostate specific antigen referrals was given section 60 support in June 2004 for a pilot study for two time periods: 1/12/2001 to 31/05/2002 and 1/12/2003 to 31/05/2004. The applicants have requested to extend this time period from 01/01/2001 to 31/05/2004 in order to improve the quality of data collection and interpretation. They also wanted to add date of prostate cancer diagnosis as an additional optional data item. The applicants had obtained Research Ethics Committee approval for this amendment.

The Advisory Group approved this extension.

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

4.9 Confidential Enquiry into Maternal and Child Health (CEMACH)

The Secretariat reminded members that as part of their last annual review in December 2004, CEMACH had asked for their Section 60 support to be extended to include another study: the *Child Death Review Project.* The Advisory Group had asked that CEMACH submit the protocol for their new

enquiry when finalised. The Advisory Group was informed that the project concerned fully identified information about deceased children.

It was agreed that it was appropriate and necessary for this project to be considered by the Advisory Group. Whilst the project would only be dealing with records of deceased children, parental consent would normally be obtained in the case of living children. As the parents would still be alive, it would be possible still to seek their consent. Members of the Advisory Group were also sensitive to the analogous relationship with the events at Alder Hey, hence the need either to use anonymised information, seek consent or apply for Section 60 support.

Members accepted the difficulty of seeking consent from parents close to the time of a child's death, and agreed it would be unethical to do so. Asking for parents' consent to use the data was generally considered more acceptable approximately 2 years after the death of the child, which increases the likelihood that the data would be incomplete which would damage the feasibility of the project. The data would be anonymised once linkage had taken place.

The Advisory Group approved the extension of CEMACH's Section 60 approval to include this project, subject to the following issues being addressed:

- Engaging with national level patient representative groups to seek their views on the project and whether this use of patient information was acceptable.
- The project included information about older children which the Group felt was highly sensitive and therefore that either the project should only include data for children under 14 years of age or that a different approach to handling this data should be taken.

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

4.10 Dangerous and Severe Personality Disorders Programme

Matt Erikson, the Home Office research manager from the Dangerous and Severe Personality Disorders programme, was in attendance to inform the Advisory Group of the programme's work. Mr Erikson explained that the programme was a collaborative initiative with the Home Office, Prison Service and the Department of Health to treat, diagnose, manage and research people with dangerous and severe personality disorders. The Programme anticipated future applications to the Advisory Group for their research projects into causes of the disorders; the relationship between the disorder and offences; and validation and evaluation of the treatment.

Mr Erikson explained that gaining consent from this group of people was problematic as patients were likely to withhold consent to their information being used, in order to be manipulative as a consequence of their disorders. Anonymised data could not be used as patient demographics were needed for

the research to be successful and these were likely to render the information identifiable.

The Advisory Group agreed that Mr Erikson's talk was extremely informative and useful in considering the particular issues related to this group and would look forward to any future applications from the DSPD programme.

5. 2005 Annual Report [PIAG 2-03(c)/2005]

The Advisory Group considered the draft Annual Report for June 2004 to June 2005. They agreed to review the Report and send the Secretariat any additional comments by the end of June.

ACTION: Advisory Group to send comments on the final version of the Annual Report.

6. Annual Review of Section 60 Regulations

The Advisory Group considered a paper on the 2005 annual review of regulations made under Section 60, including reports from the United Kingdom Association of Cancer Registries (UKACR) and the Health Protection Agency (HPA). The regulations fall into two categories, specific support and class support.

Specific Support:

6.1 United Kingdom Association of Cancer Registries (UKACR)

The Advisory Group considered the report from the UKACR describing the steps taken during the previous year to improve the way they processed patient identifiable information. The Group welcomed the progress that had been made in the last 12 months.

The Advisory Group recommended that the UKACR:

Continue the development of their communication policy in the manner described in their report and also:

- Confirm when translated information leaflets for minority groups and different formats would be available
- Report on the outcome of the planned review of the information leaflet in January 2006
- Provide a copy of the revised FAQ's
- The Advisory Group acknowledged the progress made towards the use of NHS number and asked that UKACR provide a copy of 'Migration of Cancer Data Collection Systems of NPfIT systems' that is awaiting sign off by NHS Connecting for Health.

6.2 The Health Protection Agency

The Advisory Group considered the report submitted by the Health Protection Agency, welcomed the work that had been undertaken during the previous year and acknowledged the progress that had been made in reducing the processing of patient identifiable information. The additional information regarding the National Public Health Service of Wales was approved.

The HPA were asked to report next year on the progress made in pseudonomising postcode or reducing full post code to sector level (ie remove last 2 letters) more widely across the HPA

Class Support Regulations

6.3 The Advisory Group had previously agreed that each activity carried out under the class support arrangements should be reviewed on the anniversary of the original application receiving PIAG approval. The Secretariat would then use these reports to compile a single annual submission to PIAG on progress made by the organisations.

6.4 The Secretariat reported to members that they had received reports from 60 applicants and reports from the remaining applicants were expected. The Secretariat reported that the responses received were positive and addressed all of the conditions set out by the Advisory Group. Application details would be updated on the Register of approved applications on the PIAG website in due course.

Clarifications or extensions were requested by some applicants regarding their continued Section 60 support as follows:

6.5 The Healthcare Commission's annual submission regarding the National Clinical Audit Support Programme (NCASP): the Advisory Group agreed to authorise the Paediatric Cardiac Surgery Audit to undertake annual data quality validation visits to all UK congenital cardiac centres. This approval was subject to the conditions outlined in the report, in particular that this and the other audits would be scrutinised by the Commission's Committee on confidential personal information.

PIAG also agreed to authorise the Cardiac Rehabilitation Audit to be piloted in five to ten sites later in 2005 before full roll-out in 2006 of approximately 365 sites (i.e. every coronary cardiac rehabilitation unit), which will take place over four years.

6.6 National Cancer Services Analysis Team reported that because of difficulties in accurate linkage they now require full date of birth, in order to differentiate between people with similar names living in the same postcode such as family members sharing an address. Date of birth is now a minimum requirement to facilitate linkage to NSTS for date of death. The Advisory Group agreed this change to the Section 60 support for two further projects 1-07(n)/2004 (Chemotherapy Analysis CES) and 1-07(o)/2004-2-07(q)/2004 (Cheshire and

Merseyside StHA Data Warehouse). The Advisory Group had previously agreed in March 2005 to authorise the inclusion of date of birth to projects 3-09(h)/2003 and 4-09(g)/2003.

The Advisory Group agreed to a request to expand the patient group for project 1-07(o)/2004 and 2-07(q)/2004 (Cheshire and Merseyside StHA Data Warehouse) to include all hospital admissions; all attendances for outpatient appointments, investigations or accident and emergency; all attendances at GP surgeries; and ambulance journeys (the hospital groups were initially more restricted than this).

6.7 Studies of Familial Melanoma (2-07(l)/2004)

The Advisory Group considered the researcher's report addressing issues raised by PIAG at its earlier review concerning the processing of family history information in relation to the Data Protection Act. It was agreed that the issues were satisfactorily addressed in their response. It was noted that information provided by patients concerning family members regarding their family history may be legitimately stored within the record of the patient and is not disclosable for a Subject Access Request by the family member. The Advisory Group advised the research team that for this study requiring family information, there is good reason not to seek consent from relatives to retain family history data under the name of the index patient.

The Group were referred to the guidance from The Joint Committee of Medical Genetics of the British Society for Human Genetics; Consent and Confidentiality in Medical Genetic Practice.

6.8 The Section 60 arrangements have led to improvements in the way that organisations process and store sensitive data, and have led to others investigating alternatives to obtaining identifiable information without informed consent, however there is little evidence that sufficient improvements have been made in the last 12 months that could lead the Advisory Group to recommend that the scope of the class support arrangements should be narrowed.

ACTIONS: (i) Secretariat to inform organisations of the outcome of their annual reviews
(ii) Distribute to members the guidance from The Joint Committee of Medical Genetics of the British Society for Human Genetics; Consent and Confidentiality in Medical Genetic Practice for information

7. Home Office, National Treatment Agency; Drug Intervention Programme.

7.1 The Advisory Group considered a paper provided by the National Treatment Agency for the Drug Intervention Programme [PIAG 2-05/2005]. Representatives from the Home Office, the National Treatment Agency, and the Department of Health attended to present the work of the programme and

discuss making an application for Section 60 support. The Home Office wished to access data held by the National Treatment Agency in order to research the effectiveness of the programme and therefore improve the service. The Home Office representatives emphasised that the use of the data was for medical purposes and not for government or Home Office use.

7.2 The Advisory Group considered the paper and following discussion, agreed that if the Home Office wanted to use identifiable patient information without consent that they should submit a formal application for consideration at the next meeting. This was felt to be an important principle to follow to ensure that all applicants were treated fairly and appropriately and to ensure that all the relevant issues would be considered.

The Advisory Group also wanted to stress the following:

- That the applicants consider releasing Home Office criminal justice data to the NHS National Treatment Agency (NTA) in order for the NTA to undertake the record matching process.
- That the applicants are aware that Section 60 support does not override patients' dissent and that it is a temporary measure while organisations put in place mechanisms either to use anonymised data or to seek consent.

The Secretariat agreed to write to the applicants informing them of the Advisory Group's decision.

ACTION: Secretariat to inform the Home Office/ National Treatment Agency of the Group's decision.

8. NHS Number Briefing Paper

8.1 The Advisory Group considered a paper on the use of the NHS Number by Section 60 applicants. [PIAG 2-06/2005]. Members had already provided initial comments on the paper. They were advised on the legal position of the NHS Number and in particular that the number will always have the potential to be identifiable when used within the NHS. The number should not be used outside of the NHS, without the patient's consent. The Advisory Group discussed the fact that the paper should include more information about how NHS Connecting for Health intended to use the NHS number.

The Secretariat agreed to make changes to the paper and obtain further comments from Members.

ACTION: Secretariat to obtain further comments on the NHS Number paper.

9. Monitoring visit to an Acute NHS Trust

9.1 The Advisory Group considered the report from the monitoring for an acute NHS Trust [PIAG 2-07(a)/2005]. A draft had previously been circulated and agreement from the Advisory Group was now sought. Additionally, Ms

Thomson asked the Advisory Group for their views on what information should be published.

The Advisory Group believed that the report findings highlighted a consistent problem throughout the NHS, that Caldicott and patient confidentiality principles were not given sufficient consideration at Board level within Trusts. The Chair agreed to write to Sir Nigel Crisp to bring this matter to his attention.

ACTION: Chair to write to Sir Nigel Crisp

9.2 The Advisory Group expressed concern that care be taken to make sure that the report should not identify individuals but be as detailed as possible to provide sufficient information and to comply with Freedom of Information requirements. Therefore, they agreed that the report be dealt with as follows:

- That the actual report itself is just sent to the NHS Trust
- That a summary of the main findings and issues with explanatory notes is published on the PIAG website
- That some of the main issues need to be addressed in the Advisory Group's Annual Report, including that PIAG are aware that the findings from the report are not unique to this NHS Trust.
- That consideration be given to how to bring the learning from this visit to the attention of University Hospital Trusts and others where integrated working may have raised organisational boundary issues with respect to the use of patient identifiable information.

ACTION: Secretariat to send report to the NHS Trust and to publish a summary on the website.

10.0 User Involvement Guidance

10.1 The Advisory Group were asked for their comments on the information that had been developed on *User Involvement; Information about Patients*; and *Your health records,* a patient information leaflet [PIAG 2-08(c)/2005].

The Chair suggested that Marlene Winfield, Head of Public Engagement at NHS Connecting for Health, be given the opportunity to comment on the Patient Information Leaflet to ensure consistency with the Public Information Campaign.

ACTION: Secretariat to send information leaflets to Marlene Winfield at NHS Connecting for Health.

10.2 The Advisory Group asked that the following changes be made to the leaflets:

- That the User Involvement Leaflet includes a form of words to explain that user groups that researchers consult, should have proper patient representation.

- That the leaflets make it clear that the information belongs to the patients, rather than the people using it.
- That the Secretariat tests the leaflet with a group of patients.
- That the leaflets stress that researchers must demonstrate they have Research Ethics Committee approval before applying for Section 60 support.
- That the leaflets refer to 'clinicians' rather than 'doctors'.

11. PIAG Seminar

The Advisory Group was asked to consider arrangements for the proposed PIAG seminar. It was decided that the seminar would take the form of a discussion amongst 20-30 invited attendees, raising awareness and listening to others about one particular issue or possibly a range of issues.

ACTION: The Chair and Ms Thomson to take this forward.

12. Applications for Section 60 support

12.1 Health Solutions Wales – Patient Episode Database for Wales (PEDW) extension [PIAG 2-10(b)/2005]

The Advisory Group considered an application for specific Section 60 support from Health Solutions Wales to extend the Patient Episode Database for Wales (PEDW) to include other Secondary Care datasets. Patient identified information was required for the effective operation of the NHS in Wales through PEDW.

The Advisory Group were informed of the necessity of laying revised Regulations before Parliament for Specific Support under Section 60 for this application.

The Advisory Group did have a number of concerns about the application, in particular:

- That the applicant develop an exit strategy from relying on Section 60 support.
- That they develop and implement a strategy to inform patients about how their data is used.
- That they are aware that Section 60 support does not permit applicants to release identifiable data to third parties without the patient's consent or another lawful basis (eg obtaining Section 60 support).
- That the approach to user involvement is widened and developed over the next 12 months and reported as part of the annual review.
- That they provide further information about how geo-coding data would affect its identifiability particularly in comparison to using postcode.
- That they develop a mechanism for respecting patient's objections to their data being held on the database.

ACTION: Secretariat to inform the applicants of the legal situation and the Group's comments.

The Advisory Group additionally considered the situation of the national English databases, NHAIS (Exeter system), the Nation-Wide Clearing Service (NWCS) and Hospital Episode Statistics (HES). The Group agreed that the revised Regulations should encompass their requirement for Section 60 support as previously agreed.

ACTION: Secretariat to initiate the process of laying revised Regulations before Parliament.

12.2 British Paediatric Surveillance Unit (BPSU) – Facilitation of studies of rare paediatric disorders. [PIAG 2-10(c)/2005]

The Advisory Group considered an application for Section 60 support from the British Paediatric Surveillance Unit (BPSU) of the Royal College of Paediatrics and Child Health for the facilitation of 8 epidemiological studies of rare paediatric disorders through the 'Orange Card' system active surveillance by Consultant Paediatricians.

Identifiable data were needed as the surveillance is primarily concerned with the collection and analysis of pre-existing data and does not involve direct contact with the patient.

The Advisory Group gave approval, subject to the conditions below, to the studies currently supported by the BPSU and named in this application. New applications to PIAG would be required for future studies. The Advisory Group felt it was inappropriate to relinquish its authority to the BPSU to approve on its behalf, applications for Section 60 support from researchers wishing to use the surveillance system. Members believed that the BPSU could play an important role in facilitating the application process but the Advisory Group thought it important that each research team had its own relationship with the Advisory Group to ensure that research teams were aware of their responsibilities under Section 60 and that they agreed to comply with the conditions set as part of approval. The PIAG application requirements could be streamlined by the PIAG Secretariat and incorporated into the BPSU application process. This would enable BPSU studies to be rapidly reviewed by PIAG Secretariat and only referred to the Advisory Group when necessary.

The Advisory Group accepted that for some studies very small numbers would mean that seeking consent would create data bias and mean that reliable, meaningful results could not be obtained. However, the Advisory Group was not satisfied that this was true of all studies and would like the BPSU to work with one of the research teams to test the feasibility of consent and to report to PIAG on progress in 12 months.

The Advisory Group felt that the NHS number should be used in preference to more readily identifiable data items such as initials or postcode. For the HIV/Aids study – the Advisory Group was concerned that this did not appear

to be operating in line with other HPA HIV/Aids data processing and should be using soundex coding and not initials.

The Advisory Group agreed to approve the applications subject to the BPSU carrying out the following:

- work with PIAG secretariat on appropriate streamlining of application processes.
- work with one of the research teams to test the feasibility of consent
- Review BPSU supporting documentation with advice from the PIAG Secretariat.
- Review and update the position statement / policy to reflect the legal position that research should only be undertaken on identifiable patient data with explicit consent or with Section 60 support.

- For current studies detailed in the applications, all research teams to:
  - complete a System Level Security Policy in line with the PIAG template
  - produce evidence of Caldicott Guardian Support
  - Agree to Section 60 conditions and principles
- For current studies:
  - PIND – if there is to be any further extension they need to consider how to move away from using patient names
  - MCADD, Early onset eating disorders, congenital rubella studies to consider how they might operate in future without the use of initials
  - HIV/Aids study to use soundex coding in line with adult HIV/Aids reporting
- For future studies: Avoid the use of initials and utilise the NHS number in preference to other more easily identifiable identifiers.

The Secretariat would write to each of the research teams to ensure that they are aware of their responsibilities under Section 60 and that they agree to the conditions set by PIAG including the completion of a System Level IT Security Policy.

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

12.3 Barts and the London School of Medicine and Dentistry, University of London – Outcomes of involuntary hospital admission in England [PIAG 2-10(d)/2005]

The Advisory Group considered an application from the Unit for Social and Community Psychiatry of Barts and the London School of Medicine and Dentistry for a study to assess outcomes and predictors of outcomes in patients who have been involuntary admitted to psychiatric hospital services. Section 60 support was sought because the applicants wished to examine records of psychiatric patients' who had not taken part in the research study, who are unable to provide informed consent either because they are unwell, or because they cannot be contacted for organisational reasons or because they had dissented from active participation in the research study.

The Advisory Group wished to make it clear to the applicant that Section 60 support would not be given in order to avoid efforts to obtain consent from patients, nor to over-ride dissent. Although the Advisory Group did understand that it would be extremely difficult to obtain consent retrospectively from patients, members asked that the applicants should make efforts to seek consent for prospective patients.

The application was approved subject to the following conditions:

- Patients that could be contacted should be informed of the use of their information and provided with a means of opting out if they object to this use of their information.
- The Patient Information leaflet should be amended to differentiate between consent to participate and consent for use of information for future patient recruitment.
- Where the patient is not traceable patient data should be pseudonymised (de-identified?) as soon as possible.
- Provide a System Level Security Policy or submit more local level information about security arrangements
- Be clearer about Honorary Contracts that the Trust needs to assure itself that the disciplinary procedures of Queen Mary College (as the employer) can be utilised if one of the researchers were to breach confidentiality.

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

12.4 Department of Child Health, Royal Free Hospital NHS Trust – Identifying children at risk of abuse using linked hospital and community records [PIAG 2-10(e)/2005]

The Advisory Group considered an application from the Department of Child Health at the Royal Free Hospital for a project to improve the identification and monitoring of children at risk of abuse using linked hospital and community records. Identifiable information was needed for the project to link a large number of records across a range of services.

The Advisory Group agreed to approve the application subject to the applicants providing additional information to the secretariat on the following issues:

- That they explain how the project will be integrated with Child Health Services and strengthen relationships with LSCBs and Area Child Protection teams
- That they work towards using the NHS number and if not able to complete this in 12 months to indicate when it likely
- That they give further details on how they will identify children at risk.
- That they undertake user involvement activities involving local community groups, and relevant national children's organisations.
- That they provide more detail in their security policy to include arrangements across services; an appropriate line of accountability; details

of the anonymisation technique used and arrangements to control access to the data.

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

12.5 Intensive Care National Audit and Research Centre (ICNARC) – Case mix programme [PIAG 2-10(f)/2005]

The Advisory Group considered an application from the Intensive Care National Audit and Research Centre (ICNARC) for the Case Mix Programme (CMP) to provide a national clinical database for practising, managing and commissioning critical care in the UK. The applicants were not able to seek consent from these critically ill patients who lacked capacity, either temporarily or permanently.

The Advisory Group agreed to approve the application subject to the following:

- Appropriate oversight by a DH/NHS body Caldicott Guardian
- That they work towards using the NHS number in place of other identifiers.
- That they clarify how long they will be holding identifiable information for and who the data controller is.
- That they should seek consent from patients once they regain capacity, where it is still held in identifiable form or inform patients about its use where this is no longer the case (fair processing requirement). The patient information leaflet should indicate how long data is held in identifiable form, who the data controller is, and be clear that patients have the right to dissent to this use of their identifiable information.
- That they work with NHS Connecting for Health to ensure that the Secondary Uses Service will be able to deliver an alternative route for data in the future.
- That the applicants be made aware that patient's relatives are currently not able to consent on the patient's behalf (the changes encompassed in the Mental Capacity Act which would make this possible under certain conditions do not come in, until 2007).
- That they produce a system level IT security policy which includes details on the different component systems, when they were last risk reviewed, and how they will destroy the data.

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

12.6 City University – National Gestational Age Statistics [PIAG 2-10(g)/2005]

The Advisory Group considered an application from a collaboration led by the City University for the National Gestational Age Statistics project to acquire data from NHS Numbers for Babies notifications to produce national statistics about gestational age at birth and gestational-specific survival of babies born in 2005 and subsequent years.

The Advisory Group agreed to approve the application subject to the following:

- Written confirmation of Research Ethics Committee approval
- That the applicants confirm whether they are able to use district or sector level postcode as an alternative to full postcode (the minimum data necessary for the purpose should be used).
- That the applicants develop and provide a detailed line of accountability which includes security arrangements.
- That the applicants consult user and patient groups.
- That the applicants develop a system level IT security policy, which includes details on how they will store the data and for how long.

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

12.7 Bolton, Salford and Trafford Mental Health NHS Trust – National Case Register of activity within nationally commissioned Medium Secure Adolescent Forensic Services [PIAG 2-10(h)/2005]

The Advisory Group considered an application for Section 60 support from 6 NHS Trusts led by Bolton, Salford and Trafford Mental Health NHS Trust for a National Case Register whereby activity within medium secure units can be recorded and monitored in order to ensure equity in quality of care provision across England. The applicants had stated they were unable to gain informed consent from the patients as they are mentally ill, have an antagonistic relationship with the service providers and that the case register requires 100% participation to be accurate.

The Advisory Group expressed concern that the applicants were seeking Section 60 support because patients were unlikely to give consent. The Group felt that this was not an entirely appropriate use of Section 60 and asked that the Secretariat gain further information from the applicants on the following:

- Justification of the requirement for data of 100% of patients.
- Have the applicants considered the feasibility of the required information being de-identified by a member of immediate care team before passing data to the applicants?
- To undertake more user involvement in the project and seek their views on the study design and acceptability of the use of their information
- Clarify that they do not intend to collect month of birth
- Clarify how long the data will be held in identifiable form
- That they develop a System Level IT Security Policy, which includes, risk assessment, audit arrangements, data destruction techniques and details of the merged systems with the 6 Trusts associated with the project.

The Advisory Group felt unable to approve the application until the Secretariat received this additional information.

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

12.8 Institute of Cancer Research – Data Cleansing for national study of endometrial cancers occurring after breast cancer [PIAG 2-10(i)/2005]

The Advisory Group considered an application for Section 60 support from the Institute of Cancer Research for a data cleansing exercise of a completed study into the relation of tamoxifen treatment for cancer to risk of subsequent endometrial cancer. The applicants wish to conduct further analysis and continue to require fully identified data. They are unable to obtain consent from patients as this is a historical study.

The Advisory Group agreed to approve the application subject to:

- Confirmation that this element of the protocol had Research Ethics Committee approval.
- Submission of an appropriate System level IT Security Policy and consideration of refreshing their BS7799 compliance audit]

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

12.9 National Cancer Services Analysis Team – Clinical and Geographical Analysis of Children's Services [PIAG 2-10(j)/2005]

The Advisory Group considered an application for Section 60 support from that National Cancer Services Analysis Team for the Clinical and geographical analysis of Children's Services in the North West of England.

The Advisory Group was disappointed that more detail had not been included in this application however they agreed to approve the application subject to the following conditions:

- That the research team indicate which other datasets that they propose to utilise and link data with.
- That the research team seek the views of users such as a children's forum appropriate to this study, rather than the Clatterbridge Centre for Oncology Forum.
- That the research team obtain approval for the use of this data from DH Security and Confidentiality Advisory Group (SCAG)

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

13. Any Other Business

The Advisory Group were given a briefing paper on the role of Caldicott Guardians within NHS organisations.

14. Future meetings for 2005

The next Advisory Group meetings will be on 12 September and 5 December 2005.