Minutes

PIAG
Patient Information Advisory Group

Meeting held on Monday 11 September 2006 at 10.30 am

Present:

Members: Professor Joan Higgins (Chair), Dr Tricia Cresswell, Dr Fiona Douglas, Ms Stephanie Ellis, Mr Michael Hake, Ms Ros Levenson, Ms Barbara Meredith, Professor Roy McClelland, Dr Michael Wilks.

In attendance: Dr Fiona Bisset (Scottish Executive), Dr Patrick Coyle(SCAG), Mr Sean Kirwan(DHIPU), Ms Karen Thomson (Secretariat), Dr Joan Trowell(ISB).

1. Welcome and Apologies for absence

1.1 The Chair welcomed Dr Joan Trowell from the Information Standards Board who was attending as an observer, in place of Professor Martin Severs and Dr Fiona Bisset attending as an observer from Scotland. It was noted that apologies had been received from Professor Mike Catchpole and Dr Peter Rutherford.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on Tuesday 13 June 2006 were agreed to be an accurate record.

3. Matters Arising/Action Points

3.1 The Chair reported that following the discussion in relation to the UK Caldicott Guardians Council(UKCGC) at the last meeting (Minute 3.2), she had been invited to attend the next meeting and that Ms Ellis had agreed to attend the UKCGC as PIAG's representative in future instead of attending the Information Standards Board(ISB). The Secretariat had begun to advise ISB staff responsible for developing standards, about the security and confidentiality aspects of standards implementation.

3.2 Ms Meredith asked if there had been any progress on the arrangement of a meeting to discuss issues in relation to people in secure accommodation. The Secretariat reported that this was an outstanding action and was included on the Actions list attached to the Secretariat report. Ms Meredith asked that when arrangements were made to consider the wide range of agencies across government who were involved in this area of work including the Home Office.

4. Secretariat Report

4.1 The Secretariat report was received and its contents noted.

4.2 <u>Mental Capacity Act Code of Practice</u>

The Advisory Group considered the implications of the Mental Capacity Act (MCA) and its Code of Practice for Section 60 applications. It was noted that legal advice had been sought about the interaction between the two pieces of legislation.

It was reported that the MCA imposes additional duties on researchers, which if not complied with, would make processing unlawful. Under this interpretation, consent under S.30 of MCA would not affect either the common law duty of confidentiality or DPA obligations. The view was that S.30 consent is not consent for the purposes of confidentiality but rather to participation in research. Therefore, for patients lacking capacity, where it would otherwise be practicable to get their consent, researchers would need to be able to justify their work in the overriding public interest as well as getting s.32 'assent'. [Assent relates to the permission given by consulted family members etc]. Section 60 would continue to apply therefore, to populations lacking capacity where seeking consent would be disproportionately difficult or inappropriate, as long as this would not involve treating those lacking capacity less favourably than those with capacity. The provisions in S30-34 of the MCA will apply where consent would otherwise be applied. Consent does not apply to studies approved under S60. The MCA is primarily relevant where interventions are being made and is introducing an assent process to safeguard the interests of patients lacking capacity.

The MCA does remove, however, lack of capacity as a valid reason for providing Section 60 support. There would need to be other justification. Whilst the legislation is not retrospective and consequently does not affect previously approved applications, it was agreed that it would be best practice for such aspects to be considered within the annual review process.

4.3 Academy of Medical Sciences (AMS) Symposium

The Advisory Group noted that the AMS symposium held on 24 June 2006 consisted of a series of lectures by eminent academics and counsel on various aspects of law relating to the use of patient information in research. However, by their own admission, few of the speakers, were experts in the field of confidentiality and whilst there had been an attempt to present a balanced programme, the weight of presentations was in favour of greater use of confidential patient information for medical research without consent. The programme included a session on S60 and members expressed their surprise that a representative of the Advisory Group had not been invited to share the platform for this session. The Chair reported that she had written to the two speakers concerned but that no response had been forthcoming, as yet.

The Advisory Group agreed, following the success of the Seminar in February that once the Secretariat was again fully staffed, a PIAG Symposium should be organised.

Action – Secretariat to include a Symposium in future planning for the Advisory Group

4.4 Healthcare Commission National Diabetes Patients Survey

It was noted that the National Centre for Social Research had been commissioned by the Healthcare Commission to conduct a national patient survey of people with diabetes. The questionnaires were to be sent out locally, the recommended option was for GPs to send out the questionnaires directly but there was also the option of either the PCT or one of the DH approved contractors, undertaking this work on their behalf under contract to the PCT and with an honorary contract with the practice. This involved disclosure of both demographic and clinical data (the fact a person has diabetes). The Commission sought legal advice and proposed that the disclosure could

be made without consent; on the grounds that it was for service evaluation and therefore that there was an over-riding public interest.

This is contrary to DH policy as set by Connecting for Health's National Programme Board that not only clinical but also demographic data should be treated as confidential. It is also contrary to GMC guidance, and the previously expressed view of the Advisory Group.

Members expressed disquiet that there were significant opportunities to inform people with diabetes about this use of their information, and to seek consent, as they are in regular contact with services. Moreover, it would appear, that this is based on a misunderstanding of the nature of over-riding public interest justification, which relates to public health considerations such as where there is risk from communicable disease or environmental hazard, which would not apply in this case.

Members recognised that this was a valuable activity and that the contractors would be acting as data processors on behalf of the GP practices but felt that it was not the place of the Commission to determine whether or not consent or S60 was required. Rather that the responsibility lay either with the Advisory Group to determine whether consent or S60 was an appropriate route or with Caldicott Guardians, with respect to consent to determine based on local factors such as, whether or not consent for participation in diabetes registers had been obtained that included disclosure for such purposes. It was noted that there was no compulsion on the part of practices to participate.

The Advisory Group agreed that the Chair should write to Sir Ian Kennedy and the Commissioners with a copy to the GMC to raise these issues with them.

Action: The Chair to write to Sir Ian Kennedy, the Commissioners and the GMC

4.5 National Patient Experience Survey

The Advisory Group noted that there were similar issues in relation to this as the National Diabetes Survey, although this did not involve disclosure of clinical information. Members expressed a number of concerns about what was proposed and asked the Secretariat to feed these back to the potential applicant. The Advisory Group considered whether they were content to review this by email, once more details were available or whether they wanted to defer it for discussion at the next meeting. Members felt that there were broader issues that needed consideration and whilst content to consider by email prior to the next meeting it was likely they would want to defer a decision until it could be discussed at the next meeting. It was also agreed that all members should review rather than a sub-group.

4.6 National Joint Registry

It was noted that a response to the Advisory Group's previous letter about consent rates had been received from Sir Ian Carruthers. It was noted that consent rates were to be a key performance indicator for the National Joint Registry. Members felt that this could be usefully employed for other bodies. It was agreed that the Chair would write back to David Nicholson, who had succeeded Sir Ian Carruthers as Chief Executive of the NHS to thank him and to ask for this to be considered for wider application.

Action – Chair to write to David Nicholson

4.7 UKCRC Activities Update

Members again welcomed this very useful update and raised the need for clarity about what type of information was being referred to in different circumstances, i.e. differentiating where it was referring to anonymised information, pseudonymised, identifiable or identified.

4.8 Annual Review of the Regulations

It was reported that the Annual review report and responses to the particular reports of the Cancer Registries (UKACR), the Health Protection Agency (HPA) and National Clinical Audit Support Programme (NCASP) had been approved by Chair's action following email discussion by members.

5. Chair's Report

5.1 Response to Professor Souhami's article in the BMJ

The Chair reported that she had responded to Professor Souhami's article in the BMJ with respect to use of confidential patient information in research without consent. Both the article and response were tabled for information.

6. Applications previously considered

6.1 University of Oxford Kadoorie Centre for critical care research and education: Intensive Care Outcome Network Study (ICON) [2-05(e)/2006]

This application, to establish a registry of patients discharged from intensive care units after a stay of at least 24 hours to study the long-term survival, psychological morbidity and changes in health related quality of life over time following discharge from ICUs, was considered at the last meeting and referred. The applicant was asked to consider whether an alternative approach was practicable through the ITU Coordinators. The applicant had responded that they had already explored this approach and provided justification for why it was not practicable. Members of the Advisory Group who had reviewed the application initially were asked to re-consider in light of the new information provided. It was noted that following this review, the application had been approved by Chair's action.

7. Fast track Applications

The Advisory Group noted that five applications for S60 support had been approved under the new Fast-track approval process being piloted. It was agreed that such applications should be given a reference number linked to the meeting at which the approval is reported and with an 'FT' code to indicate it is a fast track application. Revised applications would retain their original reference.

7.1 Use of Patient hospital medical record to support NHS Clinical Coding Audit – NHS CFH [3-04(FT1)/2006]

This application from NHS Connecting for Health was on behalf of all NHS Trusts in England to permit access to patient records in order to audit standards of clinical coding. In some Trusts, this activity is outsourced and involves access to patient records by staff outside of the clinical care team. Although the application was for

access to records, no identifiable data would be extracted. Whilst this application was not of direct clinical benefit to patients, this would improve the data quality for a range of purposes and access was for a very limited period. It was therefore approved by Chair's action.

7.2 Feasibility of data collection to develop methods of targeted screening of people with moderate to high risk of bowel cancer – ICR [3-04(FT2)/2006]

This application from the Institute of Cancer Research was to identify a cohort of patients who had undergone screening in order to invite them to participate in the study. Fully identified data was required in order to manage the invitation process. Whilst this study would be unlikely to benefit the cohort invited to participate, it was likely to benefit future patients. Additionally, this group of patients would have recently undergone screening and the initial approach would be from the screening programme. The application was approved by Chair's action subject to a revised application being submitted for phase 3 of the study when this would be rolled out nationally, taking on board lessons learned from the earlier phases. It was further agreed that user involvement should be strengthened; that dissenters should be removed immediately and non-responders within 12 months of being invited.

7.3 Population Flexible Sigmoidoscopy Screening: Demonstration of a high uptake nurse-led programme – St Mark's Hospital, Harrow & UCL

[3-04(FT3)/2006]

This joint application from St Mark's Hospital in Harrow and University College, London was to identify a cohort of patients within a particular age group in order to seek their participation in a research project involving screening using a flexiscope. Fully identified data was required in order to manage the invitation process. It was noted that this study was likely to be of direct benefit to the patients involved as well as future patients. This was approved by Chair's action.

7.4 BPSU: Surveillance of Fetomaternal Thrombocytopenia (FMAIT) – NPEU, University of Oxford [BPSU 03-04(FT4)/2006]

This application from the National Perinatal Epidemiology Unit at Oxford is for a study using the previously approved BPSU methodology. The identifiers required are: NHS number, hospital number, date of birth.

This application was approved by Chair's action subject to the following conditions:

- That an exit strategy for the long-term retention of data within SUS is developed.
- That consideration is given to reducing or removing Date of Birth and only retained in full if this is necessary for analysis.
- That a system level security policy is developed including proposed methods of data destruction and that consideration is given to conducting a security risk review.

7.5 British Women's Heart and Health Study - LSHTM [1-07(e)/2004]

This was a revised application for a previously approved study but where the site and sponsor for the study had changed. Formerly this project was run by the University of Bristol, however, the data and research team were to be relocated to the London

School of Hygiene and Tropical Medicine. As there were no changes to the research itself, this had been submitted for fast track approval with a revised application form, which included the new security arrangements. This application was approved by Chair's action subject to the relocated team leader continuing to have research governance responsibility, including ethical governance and confidentiality arrangements, for all staff including those continuing to have access from Bristol. Clarification as to the length of access by staff at the University of Bristol would need to be provided with a view that ongoing access should not be permitted without clear lines of accountability. Approval is also subject to efforts being made to inform the study participants of the change to the data controller although still the same study team with assurance about the continued security and confidentiality of the data.

8. Applications for Section 60 support

8.1 Cancer Research UK (Leeds Teaching Hospital Trust) – A retrospective case-control study of melanoma patients who have undergone sentinel lymph node biopsy [3-4(b)/2006]

The Advisory Group considered an application from the Division of Genetic Epidemiology at the Cancer Research UK Clinical Centre at St James University Hospital, Leeds. The study has been designed to increase understanding of Sentinel lymph node biopsy (SNB) in providing prognostic information for patients and their carers. The study is a retrospective case control study comparing clinical histopathological and tumour gene expression in melanoma patients with a positive SNB result and those having a negative SNB result. The applicant intends to collect data from multiple centres around the UK to the end of August 2006. The applicant wanted access to both data and tissue samples. As the applicant was proposing only to collect existing tissue samples, prior to 1 September 2006, the provisions of the Human Tissue Act requiring consent would not apply. The applicant was aware that S60 only relates to setting aside the common law duty of confidence with respect to the processing data and not tissue, other than for the purpose of identifying a cohort in order to seek consent for use of tissue.

The Advisory Group accepted that some processing of identifiable data was required in order to identify relevant patients, establish their vital status and for ordering tissue samples. Members were not convinced however about the arguments for not seeking consent from surviving patients. Such patients would have continued contact with services for follow up for some time and would already have anxiety about relapse. Consent should therefore be practicable and would not be inappropriate.

Another key aspect of concern related to the retention of identifiers. Whilst separating identifiers from clinical data into separate databases is acceptable as a short-term solution, in law the data is still identifiable. The Advisory Group felt that justification for retention of those identifiers beyond the short-term need for linkage and cleansing purposes had not been made. Long-term retention of identifiers was not in keeping with data protection requirements.

The Advisory Group therefore agreed to provide partial approval for the application, to enable initial identification of patients and their vital status. For living patients, still under follow up care or recently discharged (c. 3 months) consent should be sought via the appropriate clinical team or a stronger case made for why consent is impracticable or inappropriate.

For deceased patients S60 support is granted for the extraction of data from records, linkage with ONS and Cancer Registry data, and the ordering of tissue samples. A study number should be allocated to each patient's data and issued to participating centres so that anonymised samples could be returned against the study number with the participating centres retaining the key for their samples/data. Once this initial process has been completed, the identifiers file should be appropriately destroyed for deceased patients.

With respect to surviving patients, whilst consent may be used to support longer-term retention of identifiers, provided this is made clear as part of the consent process, the applicant should be mindful that currently in law consent is not enduring and would therefore need to be re-sought periodically. Approval is subject to the above and confirmation of appropriate security arrangements. Members also asked for clarification about how many patients had been consulted about the study and what changes had been made as a result of their input.

Action – Secretariat to inform the applicant of the Group's decision

8.2 British Association for Parenteral and Enteral Nutrition (BAPEN) - British Artificial Nutrition Survey (BANS) [3-04(c)/2006]

This application was for a national audit of the use of artificial nutrition to assess quality of care and outcome data as measured against the National Institute for Health and Clinical Excellence (NIHCE) guidelines. The British Association of Parenteral and Enteral Nutrition is a small independent charity of professionals, which have been undertaking this audit for ten years. Audit would ordinarily use pseudonymised data but identifiers were required for longitudinal linkage of patients. There were large numbers involved and some would lack capacity either temporarily or permanently. It was noted that consent would be feasible in some patients (in-patients) but not those in the community. Members were concerned that there was no apparent exit strategy from S60 support but recognised that there was strong user involvement and support for the audit. The Advisory Group acknowledged the importance of the audit and that although there was a lack of knowledge about issues of confidentiality and consent there was a willingness to meet requirements. Members therefore granted S60 support for twelve months, subject to the following conditions:

- To develop an exit strategy from S60 support through discussion with NHS CFH to obtain pseudonymised data from SUS. The timescale for this would be dependent on CFH.
- Depending on the timescale/practicability for the above to consider how to obtain consent from in-patients.
- To consider the implications of the Mental Capacity Act and its Code of Practice for the audit, i.e. obtaining assent from patients' representatives.
- To develop a patient/carer information leaflet to explain the work of the audit and right of opt out, for dissemination via the clinical centres and community staff.

If a longer period is required for implementation, the applicant may submit a revised application, explaining the exit strategy, timescale and the steps taken to meet the conditions.

Action – Secretariat to inform the applicant of the Group's decision

8.3 UEA- Biomedical Research Centre – A cluster randomised controlled trial to assess the effectiveness and costs of implementing asthma risk registers to identify and improve management of high-risk asthma patients in primary care. [3-04(d)/2006]

This application was for a trial to examine the efficacy of registers for high-risk asthma patients. Asthma registers already exist within general practices but this would specifically target those patients at high risk of emergency treatment or hospitalisation from asthma. There were a number of issues of concern in relation to this application. The first was that it involved a comparison of two groups of patients, one receiving routine care in general practice and the other included on these registers. This raised the question of whether consent was needed to participate in the research because the two groups were to be managed differently.

Another issue was the fact that this group of patients were in frequent contact with services and therefore consent should be practicable. The apparent justification for not seeking consent was the data bias resulting from the fact that the highest risk groups were likely not to attend regular review appointments and had adverse behavioural or psychosocial issues that meant the patients would be more likely to dissent. The definition of such behavioural /psychosocial issues was very broad and there had been no consideration of the fact that S60 is not to be used to over-ride patient dissent.

The Advisory Group agreed to refer this application and to ask the applicant to test the feasibility of obtaining consent from this group of patients or if they had already done so, to provide evidence of the outcome. The applicant should also revise their application to take account of the issues raised, in particular to document more carefully the adverse behavioural characteristics. A patient information leaflet should also be prepared and submitted with the revised application specifying the purpose of the register, that the data controller would be the PCT, that patients have the right to opt out and who to contact in order to raise concerns / access the opt out mechanism.

Action – Secretariat to inform the applicant of the Group's decision

8.4 University of Manchester – Trauma Audit and Research Network (TARN) [PIAG 3-04(e)/2006]

The Trauma Audit and Research Network (TARN) collects data from over 50% of NHS Trusts across England and Wales to monitor standards of Emergency care. It provides Trusts with outcome analysis and anonymised comparisons across the UK. Section 60 was required as minimal identifiers were required for linkage and analysis.

Members noted that considerable work had been undertaken to reduce the identifiers needed to a minimum. The Advisory Group agreed to provide S60 support for three years subject to the following conditions:

- That the applicant engages with NHS CFH to develop an exit strategy from the longer-term retention of identifiers.
- That the applicant strengthens user involvement through wider engagement with patients such as those involved in Headway or other relevant patient/ public groups. (12 months)

The applicant can request an extension in three years if a solution via SUS is not available in this timescale.

Action – Secretariat to inform the applicant of the Group's decision

8.5 Clinical Trials Support Unit, University of Oxford – HPS2 – THRIVE: Treatment of HDL to Reduce the Incidence of Vascular Events [3-04(f)/2006]

This application was for a study to assess the effects of raising HDL cholesterol with niacin plus MK0524 to offset the side effects of niacin, in order to reduce the risk of cardiovascular events, in people who already have a history of such events or risk factors.

The application was to identify the relevant cohort in order to seek their consent to participate. This application was similar to the previously approved ASCEND study from the same applicant. It was noted that the first point of contact would be from the hospital where the patient was treated but the CTSU would manage the invitation process. Details of non-responders would be removed at the end of the recruitment phase. It was noted that the applicant had not addressed the question of user involvement appropriately.

Members were not convinced by the argument of why consent was not feasible as this group of patients were in regular contact with services and as their treating consultants were collaborators in the project and should be willing therefore to seek the consent of such patients.

Action – Secretariat to inform the applicant of the Group's decision

8.6 Queen Mary, University of London – A case control audit to evaluate the impact of the NHS Breast screening programme in the W Midlands on women's risk of dying of breast cancer [3-04(g)/2006]

This application involved a comparison of screening histories of cases and controls through linkage of data held by the West Midlands Cancer Intelligence Unit, NHAIS (Exeter) and the National Breast Screening Service. Identifiers were only required for a short period to undertake linkage, establish vital status, whether they were still living in the region and to undertake some preliminary analysis such as deriving deprivation scores from postcode. Members had a number of concerns about this application, such as whether it was indeed audit, as if so, it should be an integral part of the quality assurance of the screening programme. It appeared therefore to be research but there were further concerns about the scientific validity of the study. It was agreed to refer the application to ensure that the application had been appropriately reviewed by a research panel. Further clarification was also needed about how it related to the national screening programme, why it was not feasible to seek consent from surviving women and what user involvement had or would be undertaken.

Action – Secretariat to inform the applicant of the Group's decision

8.7 Academic Unit of Anaesthesia, Leeds Teaching Hospital Trust – Study to examine non-cardiac peri-operative mortality in patients who have had prior cardiac intervention [3-04(h)/2006]

This application was to support analysis of national data for five years extracted from Hospital Episode Statistics including date of death within 12 months of non-cardiac surgery where there had been previous cardiac intervention (CAGB or PCI). The applicant required ethnicity and date of death, as date of death is in the public domain this would render other clinical information potentially more identifiable. The applicant planned to anonymise the data within twelve months. As guidance from the

Office of the Information Commissioner with respect to FOIA exemptions for records of deceased patients was still pending, it is debateable if S60 is required. However, Department of Health policy has always been that medical records should continue to be treated as confidential after death. The Advisory Group therefore agreed to approve the application.

Action – Secretariat to inform the applicant of the Group's decision

8.8 MHRA, GP Research Database – record linkage of GPRD data with ONS death data and Small area level Townsend scores [3-04(i)/2006]

This application from the Medicines and Healthcare Products Regulatory Authority was to link the anonymised GP Research Database (GPRD) with ONS mortality data and allocation of deprivation scores based on postcode. The applicant proposed that a trusted third party perform the linkage on their behalf so that the database would remain anonymised. The difficulty was that the third party had not yet been identified and therefore the Advisory Group were unable to make a judgement about whether the security and confidentiality arrangements of the third party were appropriate and could be trusted. Members felt that in principle this was an appropriate approach and would be amenable to a revised application. Members suggested that the applicant explore whether it would be feasible for the ONS to undertake the linkage on their behalf. The Advisory Group agreed that any revised submission should include stronger user involvement arrangements.

Action – Secretariat to inform the applicant of the Group's decision

8.9 MHRA, GP Research Database – Anonymisation of text from GP datasets [3-04(j)/2006]

This application from the Medicines and Healthcare products Regulatory Authority for the GP Research Database (GPRD) was to permit the GPRD support staff to check and remove identifiers incidentally collected through extraction of 'free text' areas. This issue had previously arisen in relation to the National Patient Safety Agency's incident reporting system. The Advisory Group agreed that where identifiers had not been sought but had been received incidentally because of automated data extraction of free text areas that Section 60 was not required for the receiving body to process the data to check and remove such identifiers. The Advisory Group further indicated that this was good practice and that GPRD staff were to be commended for doing this to protect the confidentiality of those patients' data prior to further disclosure from GPRD. Members felt that Section 60 was not appropriate in these circumstances as the onus should remain on the disclosing bodies, GP practices in this instance, to check data extracted from their systems prior to disclosure, to reduce the likelihood of such incidental disclosures occurring in future.

Action – Secretariat to inform the applicant of the Group's decision

8.10 Imperial College, London – Burden Of Lung Disease (BOLD) [3-04(k)/2006]

This application from Imperial College, University of London was to establish the prevalence of COPD and its principal factors in west London and to measure the burden of COPD in terms of quality of life, activity limitation, respiratory symptoms and use of healthcare facilities with a view to developing a validated model to project future burden of the disease. The applicant wanted to identify a random cohort of about one thousand patients in the relevant age group with a view to inviting them to

participate in the study. The Advisory Group recognised that these were important research questions. However, members were not convinced, given the size of the cohort, that the invitation to participate could not be handled directly by participating GP practices. The Advisory Group therefore rejected the application and proposed that funding be allocated to practices for them to invite patients.

Action – Secretariat to inform the applicant of the Group's decision

8.11 South West Public Health Observatory – Urological Cancer Registry linkage study [3-04(l)/2006]

The application was to enable the South West Public Health Observatory(SWPHO) to link cancer registry data with that of Hospital Episode Statistics (HES) and the British Association of Urological Surgeons (BAUS) in order to conduct service audit and epidemiological studies to inform patient care and planning. The analysis is similar that already undertaken within SWPHO as a cancer registry for the South West but on a national basis. The Advisory Group felt this was an appropriate extension for them to undertake this high-level linkage project. The Advisory Group therefore approved the application for twelve months.

Action – Secretariat to inform the applicant of the Group's decision

8.12 North West, Eastern and West Midlands Public Health Observatories – BMI Childhood Obesity database [3-04(m)/2006]

This application from three Public Health Observatories was for access to PCT held data, collected as part of the national childhood obesity surveillance project, for further analysis. In light of the fact that the data had already been collected for 2005/06, the Advisory Group approved the application but only for data previously collected (i.e. for the school year 2005/06) and agreed that this application could be extended to cover all eight PHOs, provided they agreed to the Advisory Group's conditions of approval. Members were clear that this would not be approved for the 2006/7 data collection as this could be undertaken with consent. It was noted, that there had been user involvement with children and young people about this project.

It was agreed that the Chair should write to the Deputy Chief Medical Officer to raise the Group's concerns about the data collection process.

Action – Secretariat to inform the applicant of the Group's decision

Action – Chair to write to DCMO

8.13 Institute for Cancer Research – Prostate cancer awareness pilot evaluation [3-04(n)/2006]

This application was to evaluate a pilot project aimed at raising awareness of Prostate cancer. It involved reviewing the uptake of PSA testing after the campaign and involved minimal identifiers for linkage / analysis purposes and identifiers would be reduced within an agreed time period following publication of their results. The Advisory Group considered this application after the meeting and approved the application subject to appropriate security arrangements being confirmed for data transfer.

Action – Secretariat to inform the applicant of the Group's decision

9. Information Governance Review Update

The Chair welcomed Mr Philip Brown who had attended to update the Advisory Group on progress in relation to general implementation of the Information Governance Review and to discuss the specific implications for the Advisory Group. It was noted that legal advice had been sought and it had been agreed that primary legislation would be required to establish the new body. Consequently, the target data for its establishment was now 1 April 2007.

Mr Brown gave an outline of the work being undertaken to implement the recommendations of the Review such as the revision of the role of Caldicott Guardians, and ensuring standards were implemented through the Information Governance toolkit.

It was noted that through legislation, the Advisory Group would be given permanent status under the auspices of the new body. Members recognised that some of the reasons for which PIAG had been established were now broader and welcomed the fact that such issues would be given greater importance. There was concern however that in the proposed new arrangements, PIAG would operate as a sub-group of the new body and therefore would no longer be accountable directly to the Secretary of State. Additionally, it was apparent that the new body would be driven by the political objective of trying to bridge different perspectives and therefore that this was likely to affect the working of PIAG.

Members expressed concern about the independence of the new body both with a remit to promote confidence in NCRS and with a scrutiny function which may lead to conflict with NHS CFH being both a supporting body and subject to scrutiny by the new body and PIAG.

It was reported that the resources for the new body would largely be an amalgamation of the resources that are currently available for the various groups coming under its remit. This was of concern to members because of the impact it would have on the work of the Advisory Group.

It was noted that the new body would have a broader responsibility for social care than the Advisory Group currently has. The interface with social care was raised as a particular issue as social care operates within a different statutory framework and with different lines of accountabilities. There were also significant variations in services, one of which was free at the point of need and the other for which payment was required in many instances. Members felt strongly that the boundary between health care and social care was one that needed to be proactively managed, with data-sharing negotiated with patients for data flows in both directions.

The new body would have a remit for England only but the Advisory Group's remit extended to cover Wales as well as England. This highlighted the issue of cross-border issues not only with Wales but also with Northern Ireland and in particular, with Scotland as a significant proportion of Section 60 applications included data collection in Scotland as well as England. It was vital that there was a consistent approach taken to data-sharing by the home nations.

The issue of how the membership of the new group would be attained was raised. It was reported that both PIAG and the Care Record Development Board (CRDB) had not been set up to have representatives. All members had been appointed through the NHS Appointments Commission. The new Board would include a significant proportion of representatives. This raised the issue of how the Board would be

publicly perceived as this could damage its credibility as an independent body. There was also the issue of how to have representatives and yet manage to keep the Board small. It was noted that the Appointments Commission process had been used to specify the range of particular knowledge and skill areas needed and this had ensured that the Advisory Group had attained a balanced membership.

It was agreed that the Advisory Group should respond formally to the proposals.

Action – Chair to write to Harry Cayton

10. UK Biobank Update

Dr Wilks declared an interest in UK Biobank as he had been invited to assist with appointing a new Chair and members for the UK Biobank's Ethics and Guidance Committee (EGC). This was not felt to be a conflict of interest.

It was reported that the UK Biobank Board had met the previous Friday and approved the report of the integrated pilot with just under 4000 participants. It had been previously agreed with UK Biobank to hold a meeting with a sub-group of PIAG to discuss the roll out of the project, with regard to recruitment at the beginning of October following submission to MREC. Dr Tim Sprosen had agreed to circulate the amended report in advance of the meeting.

11. Considering the scientific validity of applications

Members considered a paper: Considering the scientific validity of applications [PIAG 2-07/2006]. The procedure documented in the paper was agreed in principle and it was agreed that members could comment on the detail by email, with final approval to be taken by Chair's action.

12. Office of National Statistics (ONS) Update

The Chair welcomed Dr Peter Goldblatt, Ms Nirupa Dattani and Ms Gloria Brackett from the Office of National Statistics who came to update the Group about their procedures for dealing with studies at the NHS Central Register (NHSCR) receiving S60 support. The ONS offer a number of services to researchers including a tracing facility to identify the current whereabouts of patients, or whether they have emigrated, their vital status and if they have been registered as having cancer, via the NHSCR which is currently operated by the ONS. Another service offered is flagging. This is where individual study members are flagged on the NHSCR and the researcher or clinical auditors are notified when an individual either: dies and provides the cause of death, obtains a cancer registration or emigrates. Section 60 was provided in 2002 to cover all the historical studies that were already flagged on the NHSCR.

As part of the approval, the Advisory Group had asked the ONS to establish an Advisory Group to review these historical studies to ensure that these were active studies and that the data was still required. Additionally this Advisory Group would consider new applications for flagging that required Section 60 support where studies were of overriding public interest and for which consent was impractical. This would be for studies based on historical data and for which any consent could no longer be said to be valid or because the terms of the consent had not included consent for disclosure to the ONS or NHSCR for flagging.

Dr Goldblatt reported on the progress made in reviewing the current 'live' studies and that to date the Group had considered approximately another 50 applications. He reported that the Group had successfully established a number of principles for considering when consent was required, when the consent obtained was adequate in terms of including this purpose. It was noted that when researchers were requesting information about deceased patients a lighter touch was used, but for cancer registration in live patients a stronger line was asserted in terms of requiring consent.

Dr Goldblatt highlighted that there had been a number of difficult issues, for example in relation to non-response rates where consent has been sought. Response rates are often low although the vast majority that respond provide consent. Where there may be particular issues in relation to sub-groups of the population, what does the non-response rate indicate? In general, dissenters differ from consenters in demographic terms and hence the potential for data bias. One study in particular had proved to be particularly difficult. It was an extension of a previous study to include a new cohort of patients, which had received S60 support under the generic approval for historical studies already flagged. For this historical study, approval was given for the controls but not for subjects. Consent had been sought and the researchers obtained overall a good response rate at 65%. As part of this work was undertaken with respect to the non-responders, which confirmed that the non-responders had a different demographic to those who responded. As is common with research studies there were a number of invitations and reminders sent out. Each time this was done, it was apparent that the number of people actively dissenting from participation increased. This indicated that a disproportionate number of those who had still not responded would dissent. The dilemma for the ONS Advisory Group for Medical Research was therefore whether the fact that the majority had consented made it reasonable to conduct the whole of this new study without consent because of the data bias being introduced recognising that many non-responders were likely to be tacit dissenters. The solution that was found as an acceptable compromise was that the researchers would receive mortality data, on the whole cohort, that cancer registration data would be processed at the ONS for non-respondents and only data in the form of aggregate tables passed to the research team. No data would be processed for refusals and patient identifiable information would be made available for those individuals who consented to take part in the study. Members confirmed that they felt that this was an appropriate way of handling such issues but suggested that where applications proved to be so difficult to resolve in future that these should be referred to PIAG.

13. Future meetings for 2006/7

Wednesday 13th December 2006
Awayday Monday 5th March 2007
Tuesday 6th March 2007
Monday 11th June 2007
Wednesday 12th September 2007
Tuesday 4th December 2007