Minutes

PIAG
Patient Information Advisory Group

PIAG 4-02/2008

Meeting held on Wednesday 25th June 2008

Present:
Members: Professor Dame Joan Higgins (Chair), Mrs Pauline Brown, Professor Mike Catchpole, Ms Stephanie Ellis, Ms Ros Levenson, Mr Michael Hake, , Ms Susan Parroy, Professor Sir Denis Pereira-Gray, Dr Mark Taylor, Mr Terence Wiseman.
In attendance: Ms Carolyn Dewhirst (Secretariat), Mr Ian Johnstone (NIGB Secretariat, Mr Sean Kirwan, Department of Health, Mr John Sheehan (Secretariat) and Ms Karen Thomson (Secretariat).

1. Welcome and Apologies for absence

1.1 Apologies for absence were received from Dr Patrick Coyle, Dr Tricia Cresswell, Dr Fiona Douglas, Professor Roy McClelland, Ms Barbara Meredith and Dr Peter Rutherford.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on 14th April 2008 [PIAG 3-02/2008] were agreed to be an accurate record, subject to minor amendments.

3. Secretariat report

The Secretariat report was received and its contents noted.

3.1 The Redfern Inquiry – Deceased patients' records

It was noted that discussions about the issues previously reported in relation to the legal basis for disclosure of confidential patient information to the Redfern Inquiry under S251 had concluded. The barrister acting for the Inquiry agreed that it was highly unlikely that a Court would find that deceased persons' medical records were not confidential following the outcome of the Epsom & St Helier Information Tribunal and Plon v France. It was further clarified that there was nothing in S251, which prevented it from being granted to provide a shield to disclosing bodies where there was doubt as to its necessity. Consequently, the approval granted by PIAG in September 2007 stands and this has been formally confirmed to the Inquiry with a letter from Mr Mike Walker, a senior civil servant acting on behalf of the Secretary of State.

The implications of this are that, whilst it may not be necessary for requesting bodies to come to PIAG to seek approval, there is, as with data pertaining to the living, a benefit in terms of providing assurance and protection to disclosing bodies that there is a lawful basis for disclosure.

3.2 Database Monitoring Sub Group

The Advisory Group considered revised draft Terms of Reference for the Database Monitoring sub-Group to incorporate consideration of applications for use of NHS Central Register data. The revised terms of reference were agreed and will be put on the PIAG website.

3.3 National Clinical Audit Support Programme

It was reported that the National Clinical Audit Support Programme, along with PICAnet and the National Joint Registry now come under the Healthcare Quality Improvement Partnership (HQIP). The Advisory Group considered who should now be the applicant for NCASP, as arguably the Information Centre is in effect acting as the data processor on behalf of HQIP. It was agreed, following discussion, that either the data controller should be the applicant or an application should be submitted jointly by HQIP and the Information Centre for Health and Social Care would be appropriate.

ACTION: Secretariat to resolve with HQIP and the Information Centre

3.3 GP Extraction Service

It was reported that the Department of Health was undertaking a procurement process to commission a new GP Extraction Service for the NHS. This new service would support a range of secondary use purposes supporting health service management but without disrupting NHS operational activities. The central issues related to this proposal are that the "honest broker" that will be commissioned to do this requires a legal basis to receive identifiable data in order to provide a linkage and pseudonymisation service. Whilst the Department is seeking to commission a service that would automate linkage and pseudonymisation, it will additionally need a back office function to undertake data quality checks and it is likely that some pseudonymisation is likely to need to be done manually. It was noted that the new service would need to accommodate patients who wished to opt out of having their data used by such a service.

It was noted that an Independent Advisory Panel for the GPES is proposed to check that the proposed secondary uses of the data were legitimate and to ensure that the data is only used for the specified purposes. It was noted that potentially this could overlap to some degree with the role of PIAG or the Database Monitoring Group and therefore that consideration might fruitfully be given to incorporating at least some aspects of the 'gatekeeper' function to the DMsG.

It was reported that Sir Alex Markham and Dr Peter Wright, at a recent NIGB meeting

have advised that they are producing another paper on the business case around "honest brokers" on behalf of the Research Capability Programme. It was agreed that the Advisory Group should have an opportunity to review this.

ACTION: PIAG to receive paper that went to NIGB and the second paper when it is ready from Sir Alex Markham and Peter Wright.

3.4 Human Fertilisation and Embryology Bill

The Secretariat report described Section 33C of the new Human Fertilisation and Embryology Bill (HFE Bill), which would enable the Secretary of State to make regulations requiring or regulating the processing of "protected information" for research purposes by the Human Fertilisation and Embryology Authority (HFEA) or others who hold information of the same kind e.g. treatment clinics or contractors. It was noted that such regulations would need to be debated and voted on in each House of Parliament. It was further noted that S33C was similar to S251 of the NHS Act 2006 in requiring information to be anonymised or consent to be sought where practicable, having regard to the cost and technology available.

"Protected information" is information, which is held on the HFEA's register about the provision of treatment services and non-medical fertility services, the storage of gametes and embryos, and people born as a result of treatment or non-medical fertility services (i.e. protected information as defined under S31(2) of the 1990 Act).

It was noted that S33C(3) states that
"where regulations under subsection (1) require or regulate the processing of protected information for the purposes of medical research, such regulations may enable any approval given under regulations made under S251 of the NHS Act 2006 (control of patient information) to have effect for the purposes of the regulations under subsection (1) in their application to England and Wales."

The Secretariat reported that the new Bill has been framed in this way, as the Bill, and the Act, which it amends, relate to all four nations. These provisions, would allow the HFEA and others, through regulations, to disclose information pertaining to patients who have received Assisted Reproductive Technologies (ART), irrespective of the country in which they received their treatment. The intention of the Bill was not to replace the powers under S251 but rather to extend them to the other nations with respect to protected information. For treatment provided in England and Wales, the regulations made under S251 will apply from the date the Bill passes (S33A (m)(ii)) to lift the prohibition on disclosure that the previous Act and the current Bill otherwise imposes. This is until the relevant regulations have been made. The regulations, however, may continue to recognise section 251 approvals.

It was noted that regulations under the Act (once the Bill is passed) could create another mechanism by which disclosure of protected information may be authorised for England

and Wales. This would create an additional burden for many researchers, as they would still need to come to PIAG for permission to link HFEA data with other confidential patient data, assuming this has not been obtained with consent. It was noted that the Secretariat was collaborating with Departmental colleagues on the regulations and how this might best be taken forward both in England and Wales and for the other home nations.

[Note from the Secretariat: Section 33C in the Bill, as referred to above is now Section 33D].

3.5 Access to deceased persons' records PIAG 3-05/2008 (Suppl)

The Advisory Group received a Supplementary to the Secretariat report in relation to access to deceased persons' records, following issues that had arisen in relation to two applicants. The issue was in relation to where approval had been given for access to specified data (i.e. not the whole record) about deceased patients but where the treating clinician had left the Trust and the Trust was unwilling to support the process of extracting information from the records. Some Trusts were willing to provide access to the whole record to enable the researcher to extract the information but it was reported that there was inconsistency in the approach taken by Caldicott Guardians. It was noted that in both cases, the applicants had only sought access to the full record because Trusts had not responded to requests for extracted data.

It was noted that there were a number of issues which needed consideration: the probable, confidential nature of medical records beyond death; that deceased persons' records often contained information pertaining to the living and therefore there was also a need to consider their confidentiality; Trusts have a responsibility to ensure that disclosures are kept to a minimum and the need for careful definition of what purposes and degrees of access had been approved.

Following discussion, the Advisory Group agreed a process, which should be followed where these circumstances arose. This is that wherever possible, Trusts should endeavour to extract and provide the relevant data extract in line with PIAG approvals. Where this was genuinely not possible, that the approved researchers should be able to view the records and extract the data on site. Further, where on site access was not possible, it was agreed that a certified copy of the records should be sent by guaranteed delivery. Any data copied onto electronic media must be encrypted to the appropriate standard. Original records must not be sent and the post should not be used, as it is not sufficiently secure for record transfer. Once the relevant data had been extracted then the copies of the records should be securely destroyed or returned to the Trust for destruction, again using guaranteed delivery.

It was reported that many Trusts receive funding to support research activities. It was agreed therefore that those obtaining this funding should offer the support function of

extracting data from deceased persons' records. It was noted as well that copying of notes was also time consuming and therefore in many instances providing the relevant extract would be less onerous. It was agreed that the Chair should raise this issue with the NHS Chief Executive.

ACTION: Chair to write to NHS Chief Executive

The Advisory Group also agreed to provide an extension to the National Confidential Inquiry in Suicides and Homicides (NCISH) studies. This was both for the above situation where clinicians are unable to complete and return questionnaires but also for the Sudden Death in Psychiatric in-patients study with respect to its validity study to ensure case ascertainment is accurate. It was noted that this would involve reviewing the notes for approximately 50 non sudden death cases per year. The Advisory Group agreed that more information was needed with respect to the Bowel Cancer Study, as although in principle supportive, this was seeking more extensive access.

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

3.6 Acquisition and use of Mental Health data by the Doctor Foster Unit at Imperial

Following the Advisory Group's request that the Unit define more precisely what mental health data it required and provide justification, the Unit had supplied a paper for the Advisory Group to consider. The key issue of concern to the Advisory Group was that many patients come into the Mental Health system via the Criminal Justice system and specifically withhold their consent for data to be disclosed by Mental Health trusts to the GP. Whilst Members were agreeable in principle to the proposal made by the Unit that only data relating to organic conditions such as dementias would be collected. ~~A~~ as Professor McClelland had been unable to attend, it was agreed that a meeting with the Chair and Dr Aylin from the Dr Foster Unit be arranged to discuss and agree a way forward.

ACTION: Chair & Professor McClelland to meet with the applicant to seek clarification and if necessary will invite a representative of the Unit to attend September's meeting.

3.7 Work Plan

It was reported that owing to the enormous process of change that was occurring, the turnover in staff and the new work taken on the by Advisory Group and Secretariat that it was necessary to establish a few key priorities for the next twelve months in order to help manage the workload. The priorities proposed by the Secretariat were agreed.

4. Chair's Report

4.1 Consent for disclosure of confidential patient information and to be approached to participate in research (consent for consent)

The Chair reported that she had had a very constructive breakfast meeting with Professor Sally Davies, Director of Research & Development and Professor Dame Chris Beasley, the Chief Nursing Officer. Professor Davies had informed the Chair that there had been a meeting with key stakeholders from the research community and that pursuing regulations had been discussed along with the suggestion of seeking legal advice. It was agreed that Professor Davies would provide the Chair with a brief note summarising the legal advice given. Professor Davies further agreed to involve the Advisory Group, once plans had been clarified. In essence, the proposal is for NHS employed research support staff to have access to patient records with a view to identifying potential research participants. It was noted that currently the legal basis for such access is unclear. Following, discussion, members agreed that this indicated a willingness to work with the Advisory Group in finding a way forward on this issue and agreed that it was reasonable to defer publication of the updated version our guidance on Identifying research participants for the time being but that this should be kept under review. Additionally, the Advisory Group may want to consider revising the document once the proposals from DH R & D have been clarified.

4.2 Relationship between NIGB and the Advisory Group

The Chair reported that there were ongoing discussions with Mr Cayton with respect to the proposed changes in legal status of the National Information Governance Board (NIGB) and the Advisory Group both with a view to ensuring a smooth transition but also in terms of the continuing role for Advisory Group members on the new Committee of the NIGB, which would deal with Section 251 approvals and other confidentiality and secondary uses issues.

5. DMsG Report & Flagging and Tracing on the Central Register

The Secretariat provided a verbal report on behalf of Dr Coyle, who had been unable to attend the meeting. It was noted that the review of HES fields with respect to sensitivity and identifiability is only partially complete as clarification was needed on the definition of some of the fields. A full set of definitions has been provided and it is hoped to complete this task at the next meeting.

The National Strategic Tracing Service (NSTS) is due for closure; however, there are still a number of ways in which it is being used. The DMsG has asked the NSTS to be clear about the security issues surrounding its closure. It will be necessary to keep the data on the NSTS until it is certain that successor organisations are fully functional and there is full confidence in them. Some audit trail data may need to be kept for a considerable time

after closure, indeed it may be necessary to consider applying the same rules that apply to patient records. Ultimately, full destruction of the media would be required. The DMsG will continue to ask for reports on this, as NSTS may have to function for several months yet.

The DMsG is becoming familiar with applications for Central Register data. It was noted that the security information on the form is not as full as it is on other applications. It was agreed therefore to ask applicants to complete the security proforma developed for IRAS. It was noted that part of the approval is for researchers to disclose information to the Central Register, so that the research subject's record can be flagged, where otherwise information would be held confidentially. There is a need therefore to communicate with applicants that flagging should generally be included as part of the consent process.

The Advisory Group also received a briefing on the Central Register 3-04/2008 and on what authority would be delegated to the DMsG in relation to approvals under Section 251. It was agreed that the DMsG would in effect have the same authority as previously given to the ONS Advisory Group for Medical Research, specifically that it would only approve applications related to flagging and tracing on the Central Register and that where other aspects of a study needed S251 approval, a full Section 251 application would need to be made.

ACTION: **The Secretariat to produce a simple flow chart to show the applications that go to PIAG and ~~to~~ those that go to DMSG.**

6. Applications previously considered

6.1 Bowel Screening Wales (PIAG 2-05(g)/2008)

This application was referred at the last meeting. Members had advised that screening falls under direct care and therefore should only be undertaken with the consent of patients. The applicant had provided further information as to why Section 60 was required in relation to the evaluation of the screening programme. This required information not only about those attending for screening but also those who had not taken up the screening invitation. Members were concerned that the patient information letter the screening programme has been sending out suggested that "consent is implied". The Advisory Group recognised that the invitation letter could assist in providing more information about the uses of the data but that this was not a basis for implying consent.

The Advisory Group were content for Section 60 support to be given for retrospective data. This was subject to the condition that the letter of invitation be amended to clarify that even if participants decline to be screened, limited health information (if they were subsequently to develop bowel cancer) would be collected on all patients for the purposes of Quality Assuring the service provided. The letter should make clear that this would be using the NHS number and specifying what other limited identifiers would be needed. It must also be explicit that patients have the right to opt out, if they do not wish their data

to be disclosed for this purpose and the means to access the opt out mechanism. The revised letter and information materials should be submitted to the Secretariat to ensure they are appropriate.

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

6.2 Role of Pre-Existing Medical Conditions and prescribed medicines in RTAs (PIAG 4-05(s)/2007)

This application was for a pilot study to undertake a case note review to examine whether a larger study was feasible in terms of scientific validity. The applicant had requested access to review 1oo records, 50 cases with a pre-existing medical condition and 50 controls. The Advisory Group had previously been concerned that the term 'pre-existing medical conditions' had not been sufficiently defined. Members were also concerned that assumptions had been made about the feasibility of obtaining consent, which had not been tested. The applicant was concerned that the more highly defined the list of pre-existing medical conditions the more records would need to be reviewed. Following discussions with the Secretariat, the applicant had requested that 'pre-existing medical conditions' be defined as the current list of self-reporting conditions. The Advisory Group agreed that the GP would have to know which records were being reviewed, as s/he would need to give permission as the data controller for access. As the study related to a ten-year period and GPs would not know whether the records being reviewed were cases or controls, this would not create a situation where GPs would be under an ethical obligation to report individuals to the DVLA. The Advisory Group broadly supported the application but agreed that the assumption that consent was not feasible, needed to be tested. The Advisory Group therefore agreed to support the application subject to the following conditions:

- That Pre-existing medical conditions is limited to the list of self-reporting conditions.
- That in addition to the 100 records reviewed under Section 251 approval, that a parallel study is undertaken to review another 100 records with consent in order to test the feasibility of obtaining consent and thereby providing an evidence base for the Advisory Group.
- That Section (r) of the form addressing data protection issues is completed.
- That the patient information materials and consent form for the parallel study is submitted for review by Mr Wiseman.

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

6.3 National General Practice Study of Epilepsy (NGPSE) [PIAG 1-05(g)/2008]

It was been agreed at the meeting in April that the applicant should re-submit the application for Section 251 support with a more clearly defined question, relating specifically to whether any of the cohort was still receiving treatment for epilepsy. The Advisory Group had indicated that it would be willing to support this limited access but that any further interrogation of patient notes, should only be done with consent. A revised application had been submitted, although this was not quite in line with what had previously been proposed. The Secretariat reported that the application was discussed with the applicant and the following proposed as a way forward:

That the questionnaire sent to GPs was in two parts, the first part to identify whether or not the patient still had active epilepsy i.e. whether the patient had had seizures or been taking anti epileptic medication in the last five years. If the patient had not had active epilepsy in the last five years, the Advisory Group agreed that limited additional data could be extracted from the record and reported (via the second part of the questionnaire) to the researcher. Where the patient continued to have active epilepsy, then their consent should be sought for access to their medical record and for any future data collection. It was agreed that there would need to be a specified cut-off date to differentiate between the two sub-cohorts. Following data extraction and validation, the data for those who had not consented would be effectively pseudonymised.

The Advisory Group agreed that on balance, it would be better to support the data collection for those who no longer had active epilepsy and who may not wish to be reminded of their past medical history, or who may not know epilepsy had been proposed as a possible diagnosis. The Advisory Group therefore agreed to support the above proposal, subject to appropriate pseudonymisation of the data following collection.

ACTION: **The Secretariat to advise the applicant of the Group's decision.**

7. Fast track applications

The Advisory Group received a summary of the fast track applications approved [3-06(FT)/2008], since the last meeting. Members noted that the following fast track applications had been approved since the last meeting.

7.1 National Surveillance of anaphylaxis as an adverse event following immunisation (AEFI) (PIAG/BPSU 3-05(FT1)/2008.

This application for a British Paediatric Surveillance Unit surveillance study was to examine the epidemiology of anaphylaxis following immunisation in detail for the first time and to identify robust evidence of the incidence rate of the condition. This study would follow the standard BPSU methodology with the minimum identifiers feasible. It was approved by Chair's action.

8. New applications for Section 60 support.

8.1 National Joint Registry Extension of PIAG 2-05(j)/2006 resubmitted as [PIAG 3-06(b)/2008]

The Advisory Group had previously approved an application for the National Joint Registry to obtain identifiable patient data for patients who had had joint replacement surgery. The original approval was given for two years, as although the National Joint Registry (NJR) had a consent process for inclusion on the registry, not all trusts had sought consent or in some instances had not recorded consent on the NJR system. The Advisory Group's position is that explicit patient consent should be obtained for inclusion on a registry, not directly support patient care, as it involves disclosure outside of the clinical care team and because data is held in identifiable form on a long-term basis. The Advisory Group had agreed to support the NJR because they were already obtaining consent and had a clear exit strategy of obtaining consent but needed interim support while issues relating to those trusts, which had either not sought consent or had not recorded consent could be addressed. Their application had also been of exceptional quality in demonstrating their understanding of information governance issues and this had provided assurance to the Advisory Group as to the necessity of the application.

This application was seeking an extension to the previous approval, as although significant improvements had been made in the consent rates, there was still some way to go before the data was sufficiently robust for clinical audit and patient safety purposes.

It was noted that the NJR had worked with some trusts where the consent process was an issue and had developed a combined consent form to obtain both but separate consent for treatment and disclosure to the NJR. It was noted that as the National Joint Registry would now come under the purview of the Healthcare Quality Improvement Partnership (HQIP), along with the National Clinical Audit Support Programme (NCASP) that the issue of application sponsorship also arose in relation to this application. It was noted that HQIP would only have access to anonymised data.

The Advisory Group had previously written to the Chief Executive of the NHS about the issue of consent for registries and for the NJR in particular. The Advisory Group had received assurance from the Chief Executive that the NHS was required to collaborate with the NJR in obtaining and recording consent. The Advisory Group agreed it would be worthwhile writing again.

ACTION: Chair to write to the NHS Chief Executive.

The Advisory Group were supportive of the application but felt that if approval was extended for too long that it would provide a disincentive to Trusts to obtain and record consent. It was agreed therefore to approve the application but only for twelve months.

The Advisory Group also had concerns about the patient information leaflet and the inference that if patients neither consent nor dissent that the NJR will receive their data in

any case. It is important to be clear that patient dissent will be respected and that where consent is sought, in future, if patients do not respond to the consent that their data will not be included on the register. Members felt that the wording should be reviewed. Members welcomed the fact that the NJR are advising patients that if their hospital does not given them the consent form to ask for it.

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

8.2 NHSD FluLine Programme [PIAG3-06(c)/2008]

The Advisory Group considered this application from NHS Direct to obtain a download of the entire National Strategic Tracing Service (NSTS) database, which would be used for testing a new programme. Ms Levenson declared an interest as she had undertaken work on behalf of NHS Direct, although not work directly related to this project.

The purpose of the programme is to provide clinical safety and fraud prevention mechanism if a flu pandemic occurs. FluLine wish to test the system and to have periodic "dress rehearsals" to ensure the system continues to operate properly. It was noted that the proposal was that synthetic data would be used to test the system as much as possible but that real data was needed for the final testing of the system and also to test the data extraction and upload process and to ensure this could be undertaken within a week. The application was therefore to cover both this final testing phase for the system itself but also periodic data extractions from NSTS or subsequently from the Personal Demographic Service (PDS) once this was operational. The application was for access to full demographic data with the NHS number but not clinical data.

Whilst Members were supportive of the purposes of the application, they were uncomfortable with approving this use of information for the whole population. It was agreed following discussion that this decision should be undertaken formally at ministerial level. There were also a number of queries in relation to the statutory basis for the operational use of a system such as Fluline. It was agreed therefore to write to the Secretary of State setting out the Advisory Group's views and requesting a formal decision.

ACTION: The Secretariat to advise the applicant of the Group's decision and write to Secretary of State requesting a formal decision

8.3 Predicting benefit from interferon treatment: Personalised therapy for melanoma [PIAG 3-06(d)/2008]

The Advisory Group considered this application to carry out genetic testing on previously obtained tissue samples. Section 60 approval was required in order to locate the tissue samples and ask for them to be sent to the Leeds laboratory for testing.

The patients concerned, had been recruited previously to various clinical trials, and this was subsequent use of their data and tissue was outwith the terms of the consent obtained.

Members considered whether re-consenting the patients was feasible, however, they agreed that the costs and time involved in contacting the participants, was disproportionate, as they had previously given their consent to take part in research, and therefore were highly likely to give their consent again. The Advisory Group agreed therefore that the use of Section 251 powers was warranted in this instance. The application was approved therefore, subject to the following condition:

- That patient information materials, are developed and appropriately disseminated to these patients, explaining this new use of their information and tissue, and with details of who to contact should they wish to opt out.

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

8.4 Improving treatment and validating prognostic criteria of thyroid cancer (PIAG 3-06(e)/2008)

This application was for a study looking at the management of treatment and prognostic systems being used (via a systematic review of previous studies) with a view to identifying the best evidence for each management aspect and validating it by applying it to a large cohort of patients' data from the Cancer registry, the West Midlands Cancer Intelligence Unit (WMCIU). Whilst it should be feasible to undertake the analysis using effectively anonymised data, the applicant, a research fellow, was seeking approval to review patient hospital records in order to extract missing values and records for the data held by the WMCIU. It was clear, however, that this application was not being undertaken on behalf of the registry.

Members noted that there were no plans to involve service users in the study, in spite of the fact that it is also widely known that all the cancer networks have patient/user groups and that there is a patient run thyroid cancer charity.

It was also reported that in practice, it was likely they would need to check virtually all the hospital records for patients with cancer, unless WMCIU have all the information the applicant is seeking on the method of diagnosis.

Members also noted that there was a lack of clarity about usage of laptops, and what data would be held on them. The answer is confused in respect of usage of laptops and what information will be held on the laptop. Additionally, members noted that again Section (r) of the form relating to data protection principles had not been completed.

It was agreed to refer the application to explore whether other approaches are feasible which would not require approval under Section 251 approval e.g. if the registry could undertake the data cleansing and validation process internally, so that anonymised data could then be extracted and provided to the applicant to undertake this research study.

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

8.5 Linkage of National Cancer Registry data to GPRD data for cancer survival analysis (PIAG 3-06(f)/2008)

The application was for a high-level linkage of cancer registry and GPRD data to undertake cancer survival analysis. Given the very large number of patients involved, it was agreed that consent was not practicable. In light of the extensive research undertaken by the applicant, however, Members felt that having a single patient representative was not good user involvement practice and therefore that there would be benefit in establishing a patient reference group, or broadening the patient representation which could be consulted for the range of studies undertaken.

The Advisory Group agreed that the User Involvement guidance should be sent to the applicant and members hoped that the offer from Lynn Faulds-Wood, the patient representative, to assist with publicity and developing more robust patient involvement, via a patient reference group would be taken up. The Advisory Group agreed to support the application on this basis.

The Advisory Group additionally wished to clarify that such research was not entirely without risk. Whilst there was no risk of physical harm to patients, harm may result from the distress caused by the breach of confidentiality in the disclosure of confidential patient information. It was therefore incumbent on the Advisory Group to minimise such distress in permitting the common law duty of confidentiality to be set aside and that applicants were under a similar duty by minimising the extent of the breach.

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

8.6 Prognostic and predictive factors in a randomised controlled clinical trial of pre-operative chemotherapy in resectable oesophageal cancer [PIAG 3-06(g)/2008].

The Advisory Group considered this study looking at oesophageal cancer. These patients all previously participated in an MRC randomised trial to examine whether pre-operative chemotherapy was beneficial. It was found that chemotherapy marginally improved surgical rates in a sub-section of the population. The applicant for this study wanted to undertake genetic analysis on the samples previously taken for the earlier study. In order to do this they wanted access to the patient identifiable data held by the MRC Clinical Trials Unit in order to obtain the relevant tissues samples from the oncology laboratories. Although in theory, it would be possible for the laboratories to look up the study number in order to identify the relevant patients, in practice the laboratories were unlikely to respond without being given fully identifiable data for the samples. It was noted that they did not wish to use the MRC Clinical Trials Unit to identify the relevant samples as the Unit did not have the same close working relationship with histopathology, as the team in Leeds and therefore that samples would be retrieved if the request came directly from Leeds.

It was noted that the majority of the original cohort had died and that only 147 patients were surviving. The Advisory Group agreed to give partial support for the application; to trace the tissue blocks for the deceased but that consent should be sought from the living prior to the blocks being obtained and that dissent should be respected. The approval was subject to the following conditions:

- That consent would be sought from surviving patients.
- With respect to the issue of the surplus tissue, generally, it would be better to ask the laboratories holding the tissue to send what is surplus rather than the whole block, as for surviving patients the block remains of value to them. Additionally, for the deceased, other researchers may wish to obtain tissue for their research and therefore may request samples relating to the same patients.
- The tissue samples should be anonymised as the genetic testing could potentially identify germ line mutations and this should only be done with consent, if traceable.

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

8.7 Spatial analysis of obesity eight cancers (endometrium, post-menopausal breast, colorectal, gall bladder, oesophagus, pancreas, prostate) and environmental covariates in Northern England [PIAG 3-06(h)/2008]

This was a study investigating the spatial relationship between cancer and the environment, specifically in relation to obesity. Obesity data would be estimated using mathematical modelling and mapped geographically alongside cancer data obtained from the cancer registry. To do this postcode and date of birth will be needed for age and geographical analyses.

Members queried if this study had obtained ethics approval and whether precise age data was required, or whether this could be reduced to age bands. Members were also concerned about the robustness of the scientific validity in relation to the mathematical model. It was noted that the scientific validity of the study had only been reviewed internally by the research team and it was suggested that some form of external review might be helpful. The Advisory Group agreed to approve the application subject to:

- the applicant obtaining ethical approval
- completion of the data protection part of the application
- age bands being used in place of age.

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

9. Annual Review of Regulations (PIAG 03-07/2008)

The Advisory Group considered the Annual Review report and reviewed the regulations made under Section 60, including reports from the United Kingdom Association of Cancer Registries (UKACR) and the Health Protection Agency (HPA) under their Specific Regulations.

9.1 Specific Support Regulations - 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 warmly welcomed the further progress that had been made in the last 12 months. The Advisory Group recommended that the UKACR continue to receive Section 60 support.

9.2 Specific Support Regulations - The Health Protection Agency

The Advisory Group considered the report submitted by the Health Protection Agency and 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.

9.3 HPA Meningitis Study (PIAG 3-07/2008 Suppl)

The Advisory Group had received notification from the HPA of a new study to look at Meningitis. The Advisory Group was asked to consider whether this fell within the public health regulations. The purpose of the study was to examine the factors associated with developing Meningitis and health outcome data to see if they can attribute weight to the factors with a view to developing a diagnostic tool. The Advisory Group agreed that this study could be encompassed within the public health regulations. It was agreed that in future where there was any doubt as to whether a study fell within the regulations that the HPA should submit the protocol for the study for review.

9.4 Class Support Regulations

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 reported to members that they had received reports from 53 applicants to date. It was noted the Secretariat had been undertaking a review of the register to identify where applicants had failed to provide an annual review report or had failed to notify the Secretariat that when their approval was due to expire that they had appropriately anonymised and/or securely destroyed data. 70 applications had been identified where such issues remained. This project was ongoing, however, and a further letter copied to their sponsor is proposed with a follow up phone call as needed.

The Secretariat sought confirmation from the Advisory Group that where applicants continued to fail to respond by submitting their annual review report, following the above process that the Secretariat could take enforcement action by revoking their approval and requiring that the data were deleted. The Advisory Group agreed.

Other than the above issue, where annual review reports had been submitted they were generally positive and addressed the conditions set out by the Advisory Group. Clarifications or extensions were requested by some applicants regarding their continued Section 251 support and these had been reported to the Advisory Group and approved where necessary at each meeting.

The Advisory Group approved the continuation of the class regulations, as it was apparent that the NHS CFH Secondary Uses Service was not yet able to provide a solution in terms of providing pseudonymised data. It was also acknowledged that once this service was fully operational this would reduce the number of applications for Section 60 support but that there would be a continuing need for exceptions to the common law duty of confidentiality for some activities.

9.5 Secondary Uses Service and Pseudonymisation Update Report

Mr Jeremy Thorp attended the meeting to update the Advisory Group on the Secondary Uses Service (SUS) and the progress being made on working towards pseudonymisation, as part of their annual review. Mr Thorp reported that since June 2007 there had been a number of major technical and information governance developments, which were outlined to the Advisory Group. Technical improvements included better data quality checks at source, new reporting tools, improved capacity within the systems, a revised Commissioning Dataset (CDS) and a new web-based service, NHS Comparators, providing aggregate data so that different areas and providers could be compared. Information governance developments included that the SUS Information Governance Strategy had been approved by the SUS Programme Board and that four workshops had been held for NHS Informatics and Information Governance staff on Information Governance for SUS, including access controls, pseudonymisation and the plans for the move to pseudonymised output through the Pseudonymisation Implementation Project. This was planned to include a step-change through a changeover day being called 'P-day'.

Plans were also outlined including for the Pseudonymisation Implementation Project. It was noted that the programme was still on track for a basic level of pseudonymisation to be provided in Release 4 (2009), with a full range of pseudonymisation capability being developed through later releases. The requirements for a Pseudonymisation Extract Service has been developed, which will enable pseudonymised extracts to be available for external agencies including commercial organisations.

Additionally, it was noted that the Access Control Team were in the process of facilitating changes to the approach on Role Based Access Controls that had been required within the Advisory Group's conditions of approval. This will lead to restricting

the registration of SUS users through a smaller group of specialised Registration Agents (RAs) to ensure that the potential complexities of SUS registration can be satisfactorily handled.

Following Mr Thorp's verbal report, Advisory Group members were given the opportunity to ask questions. The Advisory Group enquired about pseudonymised extracts, with respect to postcode and outputs from SUS that would not identify individuals but where geographic or deprivation analysis was needed. Mr Thorp explained that extracts generally would be wholly pseudonymised and would not contain postcode data but would include derived data such as health authority, PCT, Ward Code, Super Output areas. He agreed that being about to provide deprivation scoring would be a significant improvement for users and that it was something the programme was considering how it might be delivered, but there were multiple scoring tools available.

The Chair asked about the fragmentation of secondary uses services through honest brokers for example in addition to SUS, a GP Extract Service, National Cancer Registry and one or more honest brokers to support the Research Capability Programme, had been proposed. Mr Thorp acknowledged that this might become an issue but that it was within the purview of the NIGB to ensure that there was a limit to the number of honest brokers and a strategy on what honest broker services were established. He highlighted that the work undertaken by NHS CFH had at least established a clear framework and a set of standards, which the providers of such services would have to meet in order to be given access to the data. Additionally, even if there were multiple services, properly managed honest broker services with legitimate access to the data would still be an improvement on the current situation where a greater number of organisations needed access to identifiable data.

11. Future meetings for 2008

September – Monday 8th 2008 – Seminar at 4.00 pm followed by Dinner

September - Tuesday 9th 2008

October - Monday 20th 2008

December - Monday 8th 2008

All meetings to take place at the Kings Fund, 11-13 Cavendish Sq, London.