Meeting held on Wednesday 1st June

Present

Members: Dr Andrew Harris (Chair), Dr Tricia Cresswell, Mrs Pauline Brown, Dr Tony Calland (*from item 3b*), Dr Fiona Douglas, Mr Michael Hake, Dr Colin Harper, Mr Stephen Hinde, Ms Sue Parroy, Dr Mark Taylor, Mr Terence Wiseman.

In attendance: Dr Alan Doyle *(NIGB Director),* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Deputy Approvals Manager),* Mr Mathew Fry (*NIGB Operations Manager*), Ms Vanessa Kaliapermall (*Department of Health*), Ms Melanie Kingston *(Deputy Approvals Manager)*, Mr Phil Walker (*Department of Health*)

1. Welcome and apologies

Apologies were received from Professor Michael Catchpole, Dr Patrick Coyle, Professor Julia Hippisley-Cox, Ms Stephanie Ellis, Professor Sir Denis Pereira Gray and Professor Jane Kaye.

The Committee welcomed Mr Stephen Hinde who had recently been appointed by the NIGB to be an additional member on the ECC following Professor Carol Dezateux's departure. Mr Mathew Fry was also introduced as the new NIGB Operations Manager and the Committee was informed that Ms Claire Edgeworth had recently been promoted to Deputy Approvals Manager. It was noted that Ms Melanie Kingston would be leaving the organisation at the beginning of June.

Declarations of Interest

Although no direct conflict of interest in relation to the work of the Committee, the Chair declared a potential conflict of interest in agenda item ECC 5-04(d)/2011] as Belmarsh prison was part of his coronial jurisdiction. In order to avoid any perceived perception of bias, he did not participate in the chairing, discussion and decisions made, and the item was chaired by Dr Mark Taylor.

Mr. Terence Wiseman declared an interest in the discussion related to Q research [ECC 3-04 (e)/2011] as he had been asked to act as a patient representative, separate to his role on the Committee as a lay member, on their Board in follow-up to the requirement highlighted by the Committee at its March meeting. He did not participate in the discussion.

2. Minutes of last meeting [ECC 3-02/2011] and matters arising

The minutes from the meetings held on 28 and 29 March were approved as an accurate record.

Matter arising:

<u>Access to identifiable sexually transmitted infection information</u>

The Chair provided a verbal update on his discussion with the Department of Health's legal advisor on the issue presented in the March meeting [ECC 3-02(b)/2011] on the interaction of the Health Service (Control of Patient Information) Regulations 2002 and the NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000.

The advice provided was that where identifiable sexual health information was required, the Sexual Health Directions give permission and establish the framework for such disclosures. The Directions place a duty on PCTs and Trusts not to disclose identifiable data relating to sexually transmitted infections other than for treatment or prevention purposes, and then only to a medically qualified professional or staff member acting under instruction from such a professional. Therefore if the data flowing was via PCT or Trust systems, application of the Health Service (Control of Patient Information) Regulations 2002 would not be appropriate. In such instances, the requirements of the Directions would need to be adhered to before permitting disclosure and any subsequent risks of disclosure would rest with the data controller.

Update on Q-Research application ECC 3-04 (e)/2011

The Committee were informed that the NHS Information Centre had written to the Chair around concerns regarding the extent of disclosure of HES data and concerns over their own compliance with the Data Protection Act 1998. Members discussed handling of this issue and agreed the following:

1. It was highlighted that any recommendations of support made under the Health Service (Control of Patient Information) Regulations 2002 are permissive, and do not mandate data controllers to disclose data. There is no obligation on data controllers to disclose if they have concerns, whatever advice the ECC has given the Secretary of State about the application meeting the legal requirements for removal of liability from the common law duty of confidentiality.

2. It was agreed that it is entirely appropriate for data controllers to seek to reassure themselves over the arrangements in place for data protection, and this is something to be encouraged with all data controllers in this situation as they are legally liable for any onward disclosures.

3. In response to the request about ECC thinking, it was noted that if expert advice had been available to the Committee, demonstrating a better method of achieving the purpose, it is possible that this would have been the expectation in our advice.

4. While the Committee can reconsider decisions on the basis of new information presented to it, such new information should be presented by the applicant back to the Committee, as no formal purpose is served by other parties requesting review of decisions. This should not undermine the importance of data controllers seeking to understand decisions and to suggest improved methods of managing information, but rather seeks to promote active engagement between data controllers and applicants.

5. The Committee strongly encouraged direct engagement by the NHS IC with the applicant over the points raised, and to seek to agree a mutually acceptable resolution between both parties. Once this agreement has been reached at that level, should a revised application be required, then it should be submitted back to the Committee as an amendment. At that point, the Committee will be happy to consider alternative methods of managing the data flows.

6. Based upon this specific instance, while the applicant appeared to have engaged the NHS IC when developing the proposal, it appears that not all details were clearly resolved prior to application to the Committee. The NIGB office would seek assurance from future applicants that they have discussed methodologies with data controllers prior to submission to the Committee so as to ensure that significant issues do not arise in future.

It was agreed that the Chair would write a letter to the NHS IC confirming this outcome.

2a. ECC Chair's Report [ECC 5-02(a)/2011]

The minutes for the NIGB meeting held on the 12th May would be available on the NIGB website following the Board meeting on the 23rd June. The chair also provided an update that Mr Harry Cayton, current Chair of the NIGB would be leaving on 31 May 2011. The appointment for the new Chair would be managed by the Appointments Commission and was currently in progress.

2b. NIGB Office Report [ECC5-02(b)/2011]

Fast Track applications

a. 5-02(FT1)/2011 The effectiveness of Cardiopulmonary Exercise Testing (CPET) as a preoperative risk assessment tool

This application from the University College London Institute of Human Health & Performance required access to current status of mortality and cause of death data from the NHS Central Register via the Medical Research Information Centre. This was in order to carry out a detailed service evaluation that would assess the effectiveness of CPET as a preoperative risk assessment tool when compared to other existing risk stratification metrics. Mortality data (date and cause of death) was requested to assess the ability of CEPT to predict longer-term post-operative outcome.

On balance, members agreed that due to the importance of the work the activity should take place and as participants were deceased consent would not be possible. A recommendation of provisional approval under the Regulations was made with the following conditions of approval:

1. Further linkages to be carried out on a fully consented basis for living participants. Those who are found to be living from the cohort should be informed of the use of their data and be asked to provide explicit consent if any future linkages will be undertaken. The NHS Information Centre should be engaged to determine appropriate wording for the consent form in future.

2. Posters should be displayed within the hospital to inform patients that their data may be used for audit purposes and that the activity is taking place. These should include information about how to opt out of the data linkages in order to meet the requirements of the sixth principle of the Data Protection Act.

3. Patient involvement should be carried out in order to ensure that patient views are considered in relation to the activity. Members suggested the establishment of a patient group in order to advise on this and other similar studies.

b. ECC 5-02(FT2)/2011 Measuring Harm and Informing Quality Improvement Longitudinally in the Welsh NHS

This application from Cardiff University requested support to facilitate access to patient records so as to carry out a case record review. The review would be undertaken in two

phases which involved both research nurses and physicians accessing notes. The study aimed to build upon the practice of Global Trigger Tool harm measurement in the Welsh NHS. This would be to provide reliable estimates of adverse events of harm through obtaining definitive data on harm in Wales via this case record review process.

Members noted that this was an important study and that there was a large public benefit to the proposed aims, and therefore made a recommendation of provisional support. Members raised concerns that there may not be sufficient opportunities for patients to learn that the study was taking place and register their dissent. They therefore requested that a condition of approval would involve displaying information within hospital inpatient departments in order to notify patients of the activity and inform them how to register dissent.

c. ECC 3-02(FT6)/2011 A Retrospective Natural History Study of Patients with Lysosomal Acid Lipase Deficiency/Wolman Phenotype

This application from Central Manchester University Hospitals NHS Foundation Trust aimed to characterise key aspects of the clinical course of LAL deficiency/Wolman phenotype in untreated patients. This would inform the evaluation and care of affected patients and provide a reference for efficacy studies of enzyme replacement or other novel therapies. Support under the Regulations was requested to allow data, including date of birth and date of death, to be released to the research sponsor (Synageva BioPharma) and the clinical research organisation contracted by the sponsor (Quintiles Ltd). Access to case notes by an individual outside the local Principal Investigator's team to check data accuracy was also required.

Members agreed to provide a recommendation of support with the condition that where identifiable personal data would be transferred outside of the European Economic Area, that it is the applicant's responsibility to ensure that there is an appropriate legal basis for this in line with the eighth principle of the Data Protection Act 1998.

Amendments

a. Extension to PIAG 2-07(i)/2004 Audit of outcomes after surgical procedure using linked HES data and ONS mortality data – linkage of Urological Cancer Registry dataset to HES data

This extension request from the Royal College of Surgeons proposed linkage of the HES extract held by the Clinical Effectiveness Unit to urological cancer registry data. It was noted that no additional identifiers would be required and that the activity would provide additional clinical information about the cancer. It was also confirmed that the linkage would be carried out for purposes specified within the original application. Due to these limited changes and high public interest, this was approved via Chair's action.

Update on previous applications

a. PIAG 4-08(c)/2003 - Confidential Enquiry into Maternal and Child Health.

Members had previously been informed that this activity had undergone a procurement process and the contract awarded to an academic institution. The applicant had been working with the NIGB Office to progress an application for support. The office has recently been informed that the Department of Health had halted the re-procurement process whilst a review

of the services is carried out. At present, the interim process and responsibility is being managed by the NPSA, communications have been provided to those submitting data to update them on these changes and a number of steps to manage this on an interim basis have been provided.

b. Health Protection Agency (HPA) – follow-up meeting to annual review

Members noted that a meeting with the HPA has been organised for 16 June between the HPA's Caldicott Guardian, other HPA representatives and the ECC Chair in order to discuss future annual review requirements. An update would be provided at the July 2011 ECC meeting.

Updates

a. The NIGB Office is expected to move premises to Elephant and Castle in line with efficiency savings by the end of June 2011, pending N3 connections being made available. Notification of changes to meeting venues will be provided once available.

b. The NIGB is hosting a collaborative workshop on information governance on 06 June. Members are asked to use their networks to circulate details of this workshop to their contacts/interested parties. Details are available on the NIGB website http://www.nigb.nhs.uk/nigb-information-governance-collaborative-workshop

The Office has attended the following meetings:

a. Linking data: new scientific possibilities for the biomedical and social sciences age. This discussed case studies from the RCP, SAIL and ALSPAC and was organised by the Economic and Social Research Council, Medical Research Council and the Wellcome Trust. The aim was to review opportunities for data linkages and make recommendations for the future.

b. The Office will be attending an evening session titled 'Making better use of public data for research - analysis of health data as an example'. In particular, it would review opportunities to making information more widely available and to discuss ethical implications.

3. Resubmissions

3a. Follow-up Study of the Incidence of Cancer and Mortality in Patients from the SEAS Trial (ECC 3-04 (y)/2011)

This application from Merck, Sharpe & Dohme, and as submitted by the University of Newcastle, set out details of a follow-up study to observe the incidence rates of cancer, total mortality, and mortality due to cancer over a 21 month period (from 04 March 2009 to 31 December 2009) in patients from the SEAS trial. An imbalance in cancer incidence was observed between the groups, with an excess incidence being seen in the trial group compared with the placebo group.

This application had originally been considered by the Committee at its meeting on 29 March 2011. The Committee had provisionally recommended section 251 support for access to data

from the cancer registries for patients that were found to be deceased, but agreed that consent should be obtained from those patients who were alive.

The resubmission requested that the Committee reconsider the decision made in relation to living patients. The letter proposed that consent would not be feasible for living patients and a request was made for section 251 support to be provided to allow access to cancer registry data without consent for those patients who were still alive.

This resubmission provided additional evidence and sought further review based on three grounds:

1. Other countries had permitted access

It was submitted that this multi-country study (Sweden, Denmark, Norway, Finland) had already received approval from the relevant authorities in the other countries involved to access to cancer registries for the follow-up study without patient consent.

In reviewing this point, members identified that there was no direct equivalent body to that of the NIGB Ethics and Confidentiality Committee (ECC) in other European countries. The ECC's responsibility is directly related to the common law duty of confidentiality around information generated within a healthcare setting in England and Wales and its prime function is to advise when this common law duty could be lifted in the public interest under certain conditions. The Committee were of the view that as the law is different in different countries this could have no effect on the decision of the ECC in this specific instance.

2. Undue distress

The resubmission letter specified that the imbalance in incidence of cancer in the group receiving simvastatin and ezetimibe compared to placebo might have arisen by chance. It stated that much larger clinical trials had not shown any evidence of increased cancer incidence and the view was that contacting patients at this stage might cause undue anxiety and harm by raising concern without sufficient evidence.

In response to this, members agreed that if there was a risk to patients then they should be informed and not to do so could be considered paternalistic. If the risk was confirmed and they were informed afterwards, patients might be concerned that they were not advised of the risk to their health when it was first suspected. The Committee were therefore of the view that the argument of distress, in this instance, did not provide sufficient grounds to avoid seeking consent.

3. Bias caused if a consent-based approach is pursued

The letter detailed that previous experience had shown that uptake for consent at this stage of the trial was likely to be around 65% and that this might lead to bias based on the different characteristics of those who may consent, and those who may not due to their different experiences of cancer.

Members were mindful that although consent rates of 65% had been quoted there was no substantial evidence to suggest that this would be the case for this trial. However, members agreed that it would be important to minimise opportunities for bias within the follow up study. In considering the need to avoid significant bias and the requirement that in recommending section 251 support decisions taken cannot be inconsistent with the provisions of the Data Protection Act 1998, the Committee agreed that it would be necessary for the cohort to be informed as to the use of their data for this purpose in line with the fair processing principle of

this Act. Due to the additional data provided on other trials, members felt that it would be reasonable, in this specific instance, for the applicant to pursue an opt-out approach to consent, rather than an opt-in approach, to the follow up. This would involve informing the relevant participants of the activity, and providing contact information should they wish to discuss further or register any expression of dissent. Pursuing an opt-out approach to consent through provision of information would satisfy this key legal requirement, and whilst members were mindful that there might be a small risk of bias to the study as dissent would have to be respected where appropriate, members were of the view that they would not expect to see large amounts of dissent from study participants, and therefore bias should be minimal.

Members were mindful that they had not been provided with a copy of the original consent form and agreed that this would provide insight into the expectations of the participant in relation to follow up and uses of their data. Members requested that a copy of this be provided before support could be confirmed in order to ensure that the uses proposed for follow up did not contradict any information provided within the original consent.

In conclusion the Committee agreed to recommend provisional approval under section 251 support to observe the incidence rates of cancer, total mortality, and mortality due to cancer over a 21 month period in living patients from the SEAS trial without explicit consent, subject to ensuring that living participants would be contacted in advance in order to inform them of the use of their data for this purpose and be given the opportunity to register dissent.

3b. Public Health Observatories (ECC 7-04 (a)/2010)

This application had previously been considered by the Ethics and Confidentiality Committee at its meeting in September 2010 where it had advised that it would stretch the boundaries of the Health Service (Control of Patient Information) Regulations 2002 to bring all of the activities contained within the previous application under the remit of Regulation 3. An application for class support had subsequently been advised. At the September 2010 meeting, the Committee had raised a number of issues, including:

- A host organisation (a legal entity) was to be identified who could make an application to cover the activities of the PHOs as they were not legal entities. This organisation could then establish formal data processor agreements with the individual PHOs.

- Clarity of detail over data flows, purposes and identifiable items required so that the scope for consideration would be clear.

- A core dataset to be identified that would be required for common use within all of the observatories.

- Consideration to be taken over whether it would be appropriate for a third party, such as the NHS Information Centre, to provide an equivalent of an ‘honest broker’ service to carry out the linkages and then to provide the observatories with a set of de-identified data relevant to the core functions of each PHO.

- To establish the individual activities for each PHO and identify the minimal amount of identifiable data required to achieve these purposes. Members had been of the view that this aspect was unclear within the application and it would be a matter of good practice to clearly define the data required to achieve the specific purpose. Taking this tiered approach would provide the benefit of clearly defining the activities of the PHOs and would be of benefit in any forthcoming moves towards Public Health England and

development of specific regulations to cover these broader activities. This view was also suggested as a perception was that potentially the extent of linkages was not as great as indicated within the original application.

- Members recommended that there be greater clarity over the internal information governance arrangements within all of the PHOs, with a view to establishing a common standard across all observatories. In particular, Members noted that activities within universities did not appear have a suitably strong level of equivalent information governance as in the NHS, such as a lack of confidentiality clauses, and recommended that this aspect be strengthened.

- Members had noted that patient and public involvement was limited and it was a reasonable requirement for the PHOs to strengthen this aspect; this was based upon a principle of the Committee that patients have a right to know and be involved in how their data will be used. This is also in line with the NHS Care Record Guarantee and the NHS Constitution, and Members recommended that this aspect be strengthened as there appeared to be opportunities to do so.

In reviewing the revised application, the Committee agreed that a significant amount of work appeared to have taken place to seek to resolve the implications arising from the previous review, and this engagement was appreciated. The key points from the discussion are summarised below.

1. Legal entity status

The Committee had previously indicated that the PHOs were not a legal entity in their own right and, as this was a mandatory requirement before any recommendation of support could be provided, noted that a host organisation would be required that could submit an application on behalf of the PHOs. The resubmission provided written confirmation from Dr Judy Jones (Deputy Director, Public Health Delivery Department of Health, and Programme Director, Public Health Intelligence, Leadership and Workforce Team), that the Department of Health (DH) would be the host organisation for the purposes of this application and would ultimately bear the risks of disclosure and take responsibility for governance arrangements. This would mean that the DH would be the data controller and the PHOs would act as the data processor on behalf of DH. This confirmation was welcomed.

2. Requirement for clearer purposes and data flows

The Committee agreed that there was greater clarity over the purposes and that they were sufficiently clear to fall within the requested classes of support. Members welcomed the additional information around the PHOs activities. As approval under section 251 could only be provided for specified purposes the Committee reiterated that any approval would only include those indicated within the application and that relevant additional activities/purposes would require an application for an extension

3. Identification of a core dataset

The Committee were pleased to note that the PHOs had reviewed the level of identifiable information and reduced the core dataset through removing augmented care period local ID, ordnance survey grid reference, patient's general medical practitioner, consultant code, detention category , legal group of patient, legal status classification and legal category of patient from the application. Members welcomed this move in line with the third principle of the Data Protection Act (DPA) 1998 that personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed. In reviewing the

requested items, members raised a query regarding whether sexual health and/or mental health information would be used, and sought further clarification on this point.

4. Lead PHO

The Committee noted the identification of a "designated PHO" that would be East Midlands PHO and that access to identifiable data items would only be granted to other PHOs when it became necessary, and following Caldicott Guardian approval on a task by task basis. It is understood that such decisions would include review of the extent of identifiers and there should be a clear audit trail to justify such decisions. Further clarity was sought over these arrangements.

5. Internal information governance arrangements

A point was raised that all PHOs appeared to have disparities in their notification with the Information Commissioner's Office under the Data Protection Act, both in terms of purposes and registered organisations. It is essential that before processing personal data that each relevant host organisation has the appropriate activity types included within the relevant data protection notification, therefore the Committee urged that this be reviewed and discrepancies resolved as an immediate priority. It was appreciated that the PHOs have differing hosting arrangements with differing bodies being the legal body responsible for correct data protection notification, and requested that this be reviewed and updated appropriately.

Further to this concern members were of the view that this application indicated that the DH would be the data controller (specifying the purpose and manner in which data is processed), and the PHO's would be processing the data on behalf of DH for the purposes specified within the application. However, it appeared that some PHO's would be data controllers in their own right so it was considered essential that clear lines of responsibility be set out so that all parties are aware of expectations and responsibilities.

Another aspect of the issue previously identified was that as the DH has been identified as the host organisation (data controller), with the PHOs acting as data processors on behalf of DH, a formal data processing contract should be put into place as a matter of urgency. This is in compliance with the seventh principle of the Data Protection Act as ultimately the DH would be responsible for the arrangements of the PHO processing of personal data for defined purposes. It was strongly advised that this aspect be escalated to the appropriate person within DH in order to move forwards with this aspect.

5. Patient and Public involvement

The Committee had previously noted that in the original application, engagement had been limited and it was an expectation of the Committee that this would be strengthened as this acts as a balance to the use of identifiable information without consent. They were mindful that in this specific instance this could be difficult but as this is a core principle, agreed that significant consideration of how to approach patients should be carried out, and a strategy for this presented to the Committee.

Conclusions

The Committee agreed that the work undertaken by the PHOs had a considerable public benefit and noted that the intention was for this work to be continued by the future Public Health England. The Committee were therefore mindful that it was important to agree upon an interim arrangement so that the work could continue with a secure legal basis for the processing of patient identifiable data until new arrangements were established. These

arrangements, once completed, should also provide a firm foundation for future governance arrangements which the Committee considered to be of key importance in the possibility of future merger within different bodies.

In line with this it was considered crucial that proper information governance standards were in place across all PHOs and that it was clear who would be accountable for these. Therefore the Committee requested that the PHOs work with the Department of Health to provide and implement clear and consistent governance arrangements across all PHOs.

As a whole, the Committee were highly supportive in principle of this application, however, due to the requirement of a contractual data processing agreement, and some disparities within internal governance arrangements, the framework of the Regulations meant that a recommendation of support could not currently be provided at this time as decisions taken by the Committee could not be inconsistent with the terms of the Data Protection Act 1998. It was clear that significant steps had been taken to seek to address previous Committee points, and these should now be built upon in order to ensure full compliance with the DPA.

The Committee agreed that the clarification and further actions would be required before a recommendation of support under section 251 could be provided.

Requests for clarification

1. Onward disclosure of identifiable items to other PHOs: Further clarity was requested over the precise criteria under which EMPHO would consider and make decisions to disclose identifiable information. It was understood that potentially three Caldicott Guardians had been identified and further clarity was sought on the roles of these persons once clearly identified, as the expectation is that these persons will be appropriately senior, with an appropriate level of information governance/clinical experience. Conformation was also sought that identifiable data would only be shared between PHOs for the purposes specified within the application and that requests for identifiable data from external researchers would not be granted without an appropriate legal basis.

2. Clarification was also sought on whether the intent would be to receive sexual health and/or mental health data items.

3. Justification to support why full postcode is required to be held by each PHO was also requested. Consideration should also be provided on use of partial postcode only (first 4 digits) to achieve the purpose

4. Provision of action plan, including timescales, to ensure DPA compliance. This would include the following:

    a. A formal contractual relationship to be established between DH and the PHOs to reflect the data controller and data processor relationship;
    b. Assurance that the requirements of the Data Protection Act 1998 are met within each PHO in line with this contractual agreement
    c. Clear accountability established for risks of disclosure and the adherence of standards within PHOs
    d. Clarification on whether each PHO will also be taking on data processing responsibilities or would also be acting as data controllers in their own right
    e. Ensuring all PHOs were appropriately registered with the Information Commissioner’s Officer to reflect their handling of personal data

f. A commitment to undertaking the Information Governance Toolkit within each organisation so as to ensure consistent adherence to NHS standards applicable to the processing of personal information generated within the NHS
g. Confirmation of acceptance from DH of the above conditions should be submitted to the NIGB Office

The applicant would be encouraged to share the outcome letter with DH so as to emphasise the importance of these DPA requirements being met as soon as possible, and to ensure that a secure legal basis could be provided to the processing of information by the PHOs for the specified purposes. Until this contractual relationship is in place, a recommendation of section 251 support could not be provided as this would mean a current recommendation of support would be inconsistent with the Data Protection Act 1998.

4. New applications for recommendations of support under the Health Service (Control of Patient Information) Regulations 2002 ('Section 251 support')

4a. EURO-URHIS – amendment [7-04 (b)/2010]

Context

The application set out the purpose of studying trends in population health for urban areas across nine EU countries. This population based survey set out to query whether it would be possible to obtain information on urban health indicators to produce tools for policy makers at local, national and international level. The survey period would last 8 weeks and requested support under section 251 to permit access to NHAIS in order to obtain name, GP registration, date of birth, full postcode, gender and telephone number. The data was required for the sampling frame to be able to stratify by age and gender. It was noted that all partners would be using similar population registers and therefore it was considered essential to use the Exeter system so as to allow comparability with the other partners.

This application was originally received on the 13 August 2010 and considered via the fast track procedure as it sought only demographic details in order to identify a cohort of patients and seek their consent. This application was approved subject to the following conditions of approval:

1. Checks for suitability to participate should be carried out by the relevant GP
2. The endorsement letter notifying the participant of the study must be sent by the Director of Public Health;
3. The letter must specifically state that the person does not have to take part;
4. The letter must give the option to opt out by phone call and not only by return of envelope;
5. The letter must make clear that not telephoning or writing might lead to a home visit by a researcher who is not a member of their clinical care team and that the patient can still opt out and decline the person entry;
6. The researcher visiting the home must be trained to make clear the choice to participate is entirely free and not seek to persuade the person;
7. The researcher visiting the home must identify when not to proceed and would include situations where capacity is in doubt.

Further to this approval an amendment request was submitted and initially considered by the Chair, which was subsequently referred to full Committee review. The amendment request requested the use of temporary staff to be used to carry out telephone and house visits. Additionally a request was made for the Committee to reconsider the condition requiring

checks for suitability to be made by the relevant GP due to difficulties in obtaining responses from those GPs.

Use of temporary staff

Having reviewed the large amount of documentation and changes that had taken place since previous correspondence, the Committee noted that access to patient identifiable data by temporary staff would only occur after consent had been taken from the patients. However the Committee raised concerns about the use of temporary staff and the distress this could cause to the patient if sufficient training was not provided to the staff members. Based on the premise that consent would be obtained in advance for temporary staff to approach patients, the Committee recognised that section 251 approval would not be required for this part of the study but advised that appropriate training should be given to temporary staff to ensure minimal distress to the patient.

GP suitability checks

The Committee identified that this condition had initially been introduced in order to ensure that the GP could identify dissent from an individual and ensure suitability for inclusion into the study. The Committee noted the issues raised by the applicant within the letter and were sympathetic to the difficulty experienced when approaching GPs to carry out suitability checks. However they were mindful that the study may be viewed as particularly intrusive due to home visits and therefore additional importance was placed on these suitability checks in order to provide added protection over the duty of confidentiality owed to the patients. If one GP practice would not be willing to carry out the suitability checks, members queried why another surgery could not be approached as it was noted that there would be a large number of patients who would meet the demographic inclusion criteria.

In conclusion the Committee agreed that, as alternatives could be identified that would allow the study to continue and due to the nature of the study, it was important that the additional check by the GP took place. The Committee also agreed that the balance of the public interest compared to the potential loss of trust in the NHS did not fall in favour of waiving the condition of approval. The Committee therefore declined to remove the condition of approval and therefore confirmed that if wishing to carry out the study using NHS data sources as specified in the application, that checks with GPs would need to continue.

4b. Data Linkage between electronic primary care records (THIN) and Hospital Episode Statistics (HES) using the Sapior Enhanced Trusted Third Party (eTTP) service. [ECC 5-04 (b)/2011]

This application from Sapior Ltd detailed a methodology for the de-identification and pseudonymised linkage of medical records from The Health Improvement Network (THIN) with patient records held by the NHS Information Centre (NHS IC).The linkage would be carried out using the HES-ID and the Vision ID. Section 251 support was required to allow a trained operative to visit a single representative site for each health data record format and access identifiable data to allow configuration of the eTTP service.

This application had originally been considered via the fast track process as it involved one representative from Sapior accessing data at a single site. However members had raised additional queries and concerns around the purpose and potential risk of identification of the resulting dataset and therefore requested that it be considered at a full Committee meeting.

The Committee agreed that the application appeared to detail a good solution to achieving record linkage without disclosing any strong identifiers to third parties and were supportive in principle of the development of new methods to accomplish this. However members raised concerns about how potentially identifiable the resulting eTTP data set would be and noted that they did not have any information about what this data set would contain. Additionally they requested further information on the future uses of this data set.

Members were also mindful that there could be potential for the GP to re-identify the dataset and raised concerns that this may result in GPs using the data set to identify all hospital episodes for any of their patients, including those which the patient may wish not to disclose to their GP. Additionally concerns were raised that the NHS IC may be able to identify GP related appointments for those patients included within HES. Members sought clarification over whether this two-way linkage would be possible.

Due to the questions raised about the merged dataset, its potential uses and the fact that the application may set a precedent for others to follow, the Committee requested that clarification be provided before a decision could be taken. The Committee felt that it would be beneficial if the applicant was given the opportunity to attend the July Committee meeting in person to allow sufficient information to be provided and for a decision to be taken.

4c. Linking electronic records between primary care records and cancer registry [ECC 5-04 (c)/2011]

This application from the University of Birmingham proposed to link primary care data held within the Health Improvement Network (THIN) database to cancer registry data in order to provide complete information on colorectal cancers. The data would then be used to formulate a prediction model which would aim to reduce delays in the diagnosis of colorectal cancer and improve the outcome of treatment.

Section 251 support was requested to allow the transfer of patient identifiers including NHS Number, date of birth, sex and postcode at diagnosis from GP practices for all patients, to the cancer registries in order to determine which patients were identifiable to the cancer registries. A pseudonymised data set would then be provided from the cancer registries to the researcher. Members noted that section 251 support was requested as all participating GP patients identifiers would be submitted to NYCRIS, therefore some would not be recognisable to the Cancer Registries prior to this disclosure.

The discussion raised the following points:

Support under section 251 cannot be inconsistent with the Data Protection Act 1998 and therefore applications are required to reflect that the principles within the Act have been met. Members were concerned that the application did not demonstrate compliance with the DPA principles. In particular, the Committee highlighted that the first principle requires that reasonable efforts be made to provide fair processing information to data subjects in order to ensure that they are aware of the potential uses of their data (the ‘fair processing’ principle).The sixth principle provides that data will be processed in accordance with the rights of individuals and this would include the right to register dissent in having their data processed for particular purposes, under certain circumstances.

The Committee noted that these two requirements in particular required reconsideration by the applicant as there was no fair processing information provided to patients and additionally no

mechanism to manage dissent made for patients in relation to the study. Unless this aspect could be significantly re-addressed, the Committee would be unable to provide a recommendation of support.

The Committee considered that where patient identifiable data is to be used without consent the study should seek a representative view from a relevant patient group or directly from a sample of patients themselves in order to test the acceptability of using identifiable data without consent. Any views and/or changes raised as a result of this engagement should be reflected. Members could only identify limited patient engagement and recommended that, particularly due to the size of the cohort, further views should be sought.

Members were concerned that information provided in relation to THIN detailed that data would not be disclosed outside of the GP practice in an identifiable format and that the linkage of the two datasets would effectively make the THIN dataset identifiable to the Cancer Registries. This would directly contradict the information that was provided to the data subject and as no fair processing information would be provided they would not be aware of the use of their data for these purposes.

Additionally members noted the intention to retain the THIN-NCDR linkage file at NYCRIS for a period of three years in case further, as yet unidentified, research studies required the same linkage process. Members were not convinced that this justification provided satisfactory grounds to retain the linkage file. This was in the context of the third data protection principle which requires that personal information should only be retained for as long as necessary to achieve stated purposes. Members noted that this would provide a method to identify patients within the THIN database and agreed that the applicant would need to provide specific justification to allow the linkage file to be retained for three years.

Section 251 support can only be provided where another practical alternative using either anonymised or pseudonymised data will not suffice. Members queried whether the applicant had considered all possible alternatives to disclosing demographic details to NYCRIS. For example, whether the same pseudonymisation software could be run within both NYCRIS and GP surgeries so that pseudonymised NHS numbers could be provided with both GP and NYCRIS clinical data and used to link the databases anonymously. Additionally members noted that a large number of patient identifiers had been requested in order to carry out the linkages and could not find evidence that all the specified identifiers would be required in order to carry out the linkage. Members queried whether the applicant had considered whether the linkage could be undertaken using fewer identifiable items and sought further clarification over this aspect.

Due to the issues and queries raised over the application and on the basis that there appeared to be a practicable alternative using pseudonymised data, the Committee were unable to recommend section 251 support at this time. It was advised that the applicant explore the issues and options outlined above and provide additional justification where required if the intent would be to provide a resubmission back to the Committee.

4d. Evaluation of the Integrated Drug Treatment System (IDTS) in English prisons ECC 5-04(d)/2011]

This application from Kings College London detailed an evaluation of the national IDTS programme. The study considered whether IDTS clients who left prison whilst still receiving stable doses of oral methadone or buprenorphine medication were less likely to die in the 16 weeks after release, compared with IDTS clients released after receiving full opiate detoxification. Section 251 support was requested to allow access to prison health records in

order to extract name, date of birth, date of death and ethnicity and allow mortality data to be obtained from the NHS Central Register.

Members noted that this study was originally designed to be carried out on a consented basis and that the study had formerly been following this methodology. The rationale for change specified that cuts in staffing levels meant that prison staff in certain prisons no longer had the time or resource available to seek consent.

In reviewing whether a recommendation of support can be provided under the framework of the Regulations, the Committee must be provided with sufficient evidence to justify that consent would not be feasible in order to support the lifting of the common law duty of confidentiality. It was clear that consent had previously been feasible, and it appeared that administrative issues had lead to a loss of resource to complete this activity. It was also noted that the applicant had requested that if the application was successful, then the need to seek consent from participants should also be waived where there was currently sufficient resource in place. This was not considered appropriate as section 251 support could only apply where consent is not feasible. Members also noted that it is not appropriate for a recommendation of support to be provided where the primary reason is that of administrative resource, and that recommendations of support are only made as a last resort where there are no other options. In line with this, members reiterated that a recommendation could only be provided where consent would not be possible, and noted that the study had already demonstrated that this was not the case. Therefore a recommendation of support could not be provided.

The Committee were mindful that this appeared to be an important study, and while it was unable to provide a recommendation of support in line with the comments above, suggested reviewing the methodology to identify whether an alternative approach could achieve some of the objectives of the study. The Committee discussed further that the cohort size was of concern in relation to a group defined as having been in prison and recommended that consideration should be given to a smaller consented cohort utilising the secondary outcome measures.

4e. SIGGAR1 trial (originally referenced under **PIAG 4-05 (c)/2007)**

This application from Imperial College London set out the purpose of receiving mortality and cancer information in people who were eligible to participate in the SIGGAR 1 trial but did not take part. Section 251 support was requested to enable legitimate access to date of birth and date of death. It was noted that the local collaborators would send patient name, NHS number and date of birth direct to the NHS Information Centre for the purposes of flagging on the NHS Central Register.

The SIGGAR 1 trial had recruited patients from 2004 – 2007; the main study had ended and analyses of data from the trial were almost complete. The aim of the study was to investigate the use of computed tomographic colonography (CTC) as a new imaging technique for the diagnosis of colorectal cancer and CTC use, compared against currently accepted alternatives of colonoscopy and barium enema. The current application detailed the purpose of validating the results of the main study by establishing whether those who were not randomised into the trial but were eligible for the study developed colorectal cancer. This would determine if the outcomes of the main study could be confirmed as useful in deciding whether the NHS should make provision for CTC across the country.

It was noted that the application had previously been submitted to the Patient Information Advisory Group in 2007 (PIAG 4-05(c)/2007), but the current application was not treated as a resubmission

due to the length of time and change in organisation since the first application. The initial application was not approved as further clarification was requested on four aspects

1. Clarification had been requested over the consent status of the initial trial participants. The current application confirmed that the initial clinical trial was fully consented.

2. Clarification had also required on whether information on those individuals who expressed dissent information was retained. It was subsequently confirmed that this information was held at the local units and would not be available to the research team at Imperial. It was noted that approximately 10% of patients had declined to take part in the study.

3. Members had queried whether the cancer registries could provide pseudonymised information, and it was confirmed that the NHS Information Centre would be providing the information to the researchers with minimal identifiers

4. Improved user involvement had also been requested, and members noted that a limited amount had taken place in the interim period. .

Members were satisfied with the additional information provided in the resubmitted application and welcomed the additional user involvement and that those who had initially dissented would not have their data disclosed to researchers at Imperial. Based upon the considerations above, the Committee agreed to provide a recommendation of support to this study.

4f. Improving Prevention of Vascular Events in Primary Care: IMPROVE-PC [ECC 5-04 (f)/2011]

This application from the University of Leeds aimed to explore the recording of cardiovascular information between primary and secondary care and the relationship between patient management and health outcomes. Section 251 support was required for access to identifiable GP, MINAP and HES data in order to identify participants and to allow linkages to be made across the databases. NHS number, hospital ID and date of death would be used to link datasets.

The Committee noted that the research team would only receive anonymised records and that linkages would take place within the GP surgeries. Members considered that the application reflected, for the majority, a good understanding of key information governance issues and that there would be minimal exposure to patient identifiable data.

Members noted that the application did not include the IRAS question concerning service user involvement and therefore requested further details about user involvement from the applicant. The Committee also noted the requirement for fair processing contained within the first principle of the Data Protection Act 1998 and recommended that patient information leaflets/posters should be displayed within GP practices to inform patients that the study was being undertaken, and that if any individual dissented from the use of their data then a mechanism should be in place to manage such dissent.

Based upon the high public interest in this activity being carried out and general good governance practices, the Committee agreed to provide a recommendation of provisional support to this application. This was subject to clarifying current and/or future service user involvement and provision of a plan to manage this, and provision of suitable fair processing information within GP practices.

4g. Extended follow-up of three occupational cohorts [ECC 5-04 (g)/2011]

This application from the Medical Research Council detailed an extended follow-up to a study originally undertaken in the 1980's to determine patterns of mortality and cancer incidence in three historical cohorts of workers exposed to phenoxy herbicides, styrene and formaldehyde. Section 251 support was requested to allow updated mortality and cancer information about the previously flagged cohort to be disclosed from the NHS Central Register in an identifiable format, and linked with data already held on individuals exposure to chemicals. Once the files had been linked to the original cohort they would be anonymised for analysis.

Members agreed that this was an important study and that it would be in the public interest for it to continue. It was noted that the study had originally began with the consent of workplace representatives rather than the participants themselves, however it was agreed that when the study began in the 1980's there was a different legislative provisions for the requirement of consent. Members discussed that many of the original cohort members would have died and that the applicant had raised concerns that excluding those who were living but could not be contacted would bias the sample. Members agreed that due to the historical nature and size of the cohort and the fact that many would be deceased, seeking consent would be particularly difficult.

Members agreed that on balance the public interest in the study was significant enough to allow the duty of confidentiality to be set aside in this instance. However members were mindful that the requirements of the Data Protection Act 1998 would need to be met, particularly those of fair processing and the right of the individual to register dissent given that individuals had never been informed about the use of their data for this study, and therefore agreed that where the correct address was known to be held for the living, reasonable efforts should be made to inform them that the study was taking place and that if any dissent was received then this should be respected.

This application was therefore recommended for provisional approval subject to the condition that suitable fair processing arrangements are to be put in place.

4h. Chest pain feasibility study [ECC 5-04 (h)/2011]

This application from the University of Bristol set out a pilot study to determine whether it would be feasible to get GPs to complete a template when presented with new patients reporting chest pain, in order to collect the data required to develop a decision rule for the appropriate referral of patients to hospital-based chest pain clinics. Section 251 support was requested in order to allow a researcher access to GP records in order to identify participants and extract identifiers to allow linkage to HES and MRIS data.

Members reiterated that a recommendation of support could only be provided where consent was demonstrated not to be practicable and where pseudonymised data would not suffice. Members considered the information provided by the applicant and agreed that they could not see any clear evidence that consent would not be feasible or that it would generate considerable bias for this particular study. In particular, GPs would complete the template when the patient presented, and therefore there appeared to be every reasonable opportunity to seek consent at that time. Members reviewed the applicant response that set out the risks of potential bias related to other studies, however, they could not determine whether they would directly correlate to this particular study or whether the studies quoted were similar in nature. Members were therefore not persuaded that consent would not be practicable.

Members noted the applicants stated that by asking for consent there might be a considerable number of patients dissenting and this would prevent a representative sample from being obtained. However members reiterated that section 251 support could not be used to override dissent. A view was also raised that due to the small number of GP surgeries participating there would be a chance that the sample might not be representative anyway. Additionally, as a feasibility study was detailed members queried whether 100% ascertainment would be required in order to provide the proposed outcomes of the study. Further to this members discussed that as the proposed activity was a feasibility study to test whether GPs would complete a template, then there was also potential for the study to be used to test whether seeking consent through GPs would be feasible. This could then provide evidence to inform the design of the full study.

In conclusion, the Committee were of the view that the argument that the GPs would not present the information in a consistent and unbiased manner was an educational issue which could potentially be addressed in the planned training sessions. Members did not consider that this should constitute a reason to override patient confidentiality. As a whole, it was agreed that there was a lack of evidence that consent would not be possible for this study and that it would seem that an opportunity existed to test the feasibility of consent. In line with this, the Committee was unable to recommend section 251 support as consent appeared feasible.

4i. Genetic testing for familial hypercholestorolaemia in high risk group [ECC 5-04 (i)/2011]

This application from University College London set out the purpose of a study to test how acceptable and efficient it is to use a saliva sample DNA testing kit to discover new cases of familial hypercholesteroaemia (FH) in a population of people who have had heart attacks. Suitable participants were to be identified on the MINAP database and sent out invitations to participate in the study. Section 251 support was requested to enable legitimate access to name and address of potential participants. Currently, the invitation process is managed by the local MINAP staff which does not require section 251 support as researchers only receive information after consent (recruiting patients from the Heart Hospital). However this application was submitted after difficulties had been experienced in getting the same level of commitment from MINAP staff at Southampton Hospital. The request was to allow researchers from UCL to receive identifiable information prior to consent in order to send out invitations to participate in the research study.

Members highlighted that a recommendation of support under section 251 can only be provided where there is no other practicable alternative to conducting the work using patient identifiable data without consent. Members were of the view that as one hospital had demonstrated that it was possible for MINAP staff to manage the invitation process, therefore not breaching patient confidentiality, there appeared to be a practicable alternative to the disclosure of patient identifiable data. Members could therefore not justify a recommendation of support in this circumstance.

Members suggested that participants could be recruited using a different hospital site, where it would be possible for local MINAP staff to manage the process without breaching confidentiality. It was also advised that the local R & D department should be able to assist in identifying another suitable site. Additionally the Committee raised concerns that the application stated that no user involvement had taken place in relation to the study. It was agreed that where patient identifiable data was to be disclosed without consent, obtaining patient involvement was particularly important as it would act as a counterbalance to processing confidential patient information without consent.

In conclusion, due to the fact that there seemed to be a practical alternative through approaching a different site, and this would not involve disclosure of patient identifiable data outside the local MINAP team, the Committee were unable to recommend section 251 support in this instance.

4j. Colorectal cancer screening equity audit for Coventry and Warwick [ECC 5-04 (j)/2011]

This application from NHS Coventry proposed an equity audit of uptake of colorectal screening in Coventry and Warwickshire, in order to inform a social marketing campaign which would specifically target localities and social groups with a low uptake. Section 251 support was requested to receive the following identifiable data items for patients invited for colorectal cancer screening in 2008/2009 – 2010/2011; address, full postcode and GP practice, as well as details of the invite to screening and uptake. Full postcode was required in order to utilise social segmentation software to generate an accurate profile of the target population for the marketing campaign.

Members considered that the project would result in beneficial outcomes. However it was discussed that there appeared to be some fundamental information missing within the application form. The Committee could not identify what the specific data flows would entail, for example it was not clear where the data would be obtained from and therefore why the organisation currently holding the data could not carry out the analysis. Additionally members could not identify the size of cohort and therefore the level of disclosure. The overall purpose also appeared unclear, for example, what exact socio-demographic differences the applicant was interested in discovering. Members considered that further detail should be provided in relation to this. It was also queried why postcode and address were required for analysis and members advised that distinct reasons for each identifiable data item would be required in order to ensure that the level of identifiable data was necessary for the purposes of the application. Concerns were raised over the lack of patient and service provider involvement within the application and members advised that this should be undertaken in relation to the activity. In addition, Members were concerned that the application did not demonstrate compliance with the DPA principles.

Members agreed that although supportive in principle of the application it required further information about the use of identifiers, data flows and detailed purpose of the application, and until this clarity was in place were unable to provide a recommendation of support at this time.

4k. North East Bowel screening cancer study [ECC 5-04 (k)/2011]

This application from Northumbria NHS Trust detailed an epidemiological review of all colorectal cancers within the North East of England who could have potentially been screened through the national Bowel Cancer Screening Programme (BCSP). Section 251 support was requested to allow a researcher access to NHS Number in order to link the Northern Colorectal Cancer Audit Group (NORCCAG) and the bowel cancer screening database from the local hub to obtain surveillance history on those patients with colorectal cancer.

Members noted that NHS number would be the only identifier provided to an external researcher for the purposes of this data linkage. However members queried whether, in the circumstances, the release of this administrative identifier would be justified in terms of the potential benefits. Members could not find evidence of a substantial benefit to the public and were therefore unsure whether it was in the public interest that the confidentiality of the patients involved would be overridden. It was also noted that the application did not fully demonstrate compliance with the requirements of the Data Protection Act (DPA) 1998.

Members were mindful that section 251 cannot be provided where applications are not compliant with the DPA and agreed that they could not conclude that in this case all the principles had been met.

In reviewing practicable alternatives, the Committee queried whether the completed data set might already exist at a national level, for example within the cancer registries, and whether an anonymised subset of this data could be provided to the applicant. Further to this the Committee suggested that the data linkage could be carried out by the applicant using pseudonymised data with the cooperation of NORCCAG and BCSP. Questions were raised as to whether it would be possible for NORCCAG to provide BCSP with a list of NHS numbers and correlating study numbers which could then be used to provide the researcher with two datasets containing only the correlating study number as the link between the NORCCAG and BCSP data set. Members agreed that by utilising this methodology no patient identifiable data would be disclosed and therefore section 251 would not be required.

In conclusion the Committee were unable to provide support at this present time due to the issues raised above, and primarily because options to use pseudonymised data needed to be explored further.

4l. Using evidence to reduce risk of healthcare acquired infection following primary hip replacement 5-04 (l)/2011

This application proposed linking data from several data sources (the National Joint Registry (NJR), the Health Protection Agency Surgical Site Infection Surveillance Service (SSISS) database, Hospital Episode Statistics (HES), Patient Reported Outcome Measures (PROMS) and ONS mortality data) in order to allow the assessment of the cost-effectiveness of infection control strategies for hip replacements performed in NHS hospitals, and to make recommendations about which infection control strategies should be implemented. Section 251 support was requested as name, NHS number, date of birth, postcode and date of death were required for linkage purposes.

The Committee noted that this was presented as a separate application rather than as part of the Health Protection Agency specific support under the Health Service (Control of Patient Information) Regulations 2002 as these made provisions for surveillance of communicable diseases, whilst this appeared to go beyond the boundaries of that support. A view was raised that the work could be seen as research, however it was noted that an opinion from NRES had been sought and that the activity had been classified as service evaluation, therefore the Committee accepted that an application for REC approval would not be required.

While the Committee welcomed the involvement of the Health Technology Assessment grant panel in the review of the study which included lay members, the Committee commented that a patient group representing the cohort could also be approached for their input into the study design and the use of patient information without consent. In reviewing whether consent would be feasible, it was noted that there were around 30,000 patients involved in the study and therefore members agreed that obtaining consent from each individual would not be feasible.

On balance, members considered this to be a highly important study and agreed that in this instance it was in the public interest to allow the duty of confidentiality to be overridden. Provisional support under section 251 was therefore recommended subject to suitable engagement with a relevant patient information group.

5. Items for consideration

5a. Amendment request - Confidential Inquiry into premature deaths of people with learning Disabilities [ECC 6-02 (FT2)/2010]

This application from the University of Bristol set out the purposes of a confidential inquiry being carried out in the Avon area. Section 251 support was requested to allow access to contact details so that the team could identify the relevant healthcare services, the provision of information about the circumstances of death to the team, and to make contact with families of the deceased where appropriate. In addition to groups with learning disabilities a comparator group would be required that did not have learning disabilities but that had died prematurely. The original application detailed that this group would be identified and their families approached by the relevant GPs and therefore section 251 support had not been required for this group.

The following amendments were requested to the original application:

1. To access GP registers in order to identify those who have died prematurely without learning disabilities, for inclusion into a second comparator group.

2. To approach families of the deceased via a letter from the confidential inquiry (CI) team, rather than via a health professional known to them.

The amendment request had initially been processed via the fast track process where members had highlighted concerns and requested that it be considered at full Committee meeting. A subsequent request for information following member concerns had been sent to the applicant in relation to the possibility of a GP covering letter being supplied with the initial letter to patient's family members. The response detailed three reasons why a covering letter could not be provided by the GP:

1. Due to the nature of the methodology, a potential conflict of interest could mean that the GP surgeries might be reluctant to pass on information about the confidential inquiry to families.

2. That approaching those without learning disabilities with a GP covering letter would be contrary to anti-discriminatory legislation

3. The GP would not necessarily know the family members of those who had died and a degree of discretion might be required, particularly if there were queries or concerns about the support that their relative had received.

Members discussed this application at length and recognised the importance of the study taking place and the potential benefits it potentially had to patient care. They considered whether it would be acceptable for researchers to have access to identifiable data for the purposes of identifying participants and additionally whether it would be acceptable for family members of the deceased to be approached directly by the CI team.

Members were mindful that some confusion may be caused to comparator group families if a letter was sent directly from the CI team as the inquiry was for those with learning disabilities. Members raised concerns that this confusion may cause distress amongst those whose family members had recently died. Members were also of the view that due to the potential grief that may be caused it would be important that the initial approach included an explanation from a health care professional responsible for the deceased persons care. In line with this, it was agreed that it would be reasonable for the CI team to access registers in order to identify those

who had died and address letters to the patient's family from the GP practice, as long as a GP covering letter introducing the study was provided with the CI letter.

In line with the comments above, it was agreed to recommend provisional approval to facilitate access to GP registers in order to identify those who had died prematurely without learning disabilities. This was subject to the condition of approval that the CI team should work with GP surgeries to write a covering letter in the GP name to include with the initial Confidential Inquiry letter. An example of this letter and REC approval for this amendment should be submitted to the NIGB Office when available.