Meeting held on 27 April 2010

Present

Members: Dr Andrew Harris (Chair), Mrs Pauline Brown, Dr Tony Calland, Dr Patrick Coyle, Professor Sir Denis Pereira Gray, Ms Sue Parroy, Dr Mark Taylor.

In attendance: Dr Alan Doyle (NIGB Director – in attendance for agenda item 1), Ms Natasha Dunkley *(Approvals Manager),* Mr Paul Eveson *(Department of Health),* Ms Melanie Kingston *(Deputy Approvals Manager),* Mr Andrew Lall *(Deputy Approvals Manager),* Ms Zoë Lawrence *(NIGB Business Manager,* Ms Karen Thomson *(NIGB IG Lead),* Mr Sean Kirwan *(Department of Health)*

1. **Welcome and format of meeting**

The following provided apologies: Professor Carol Dezateux, Ms Stephanie Ellis, Mr Michael Hake, Ms Ros Levenson, Professor Roy McClelland and Mr Terence Wiseman.

1. Research Capability Programme 'honest broker' pilots

Mr Peter Knight and Ms Kerrie etc etc attended the meeting to provide a presentation of the Research Capability Programme Honest Broker Pilot. This represented a starting dialogue with the Committee and aimed to set out an overview of the functions and services of the pilots.

Mr Knight highlighted that the overarching aim of the programme was to provide access to information in a controlled manner that would maintain the privacy of records. It aimed to bring a number of disparate datasets together and then disclose primarily anonymised information to applicants. It was indicated that the intention would be to provide an application to teh Committee at its July 2010 meeting, and therefore this aimed to provide some background to the activity.

All studies involved with the pilots would have obtained the necessary scientific, ethical and legal approvals prior to any disclosure taking place, and it was clear that any onwardly disclosed data would be use for specific and defined purposes.

In terms of the approach, the programme would work with the NHS Information Centre, Cancer Registries, the Health Protection Agency and Small Area Health Statistics Unit. This would be in order to identify how the concepts fit together and to identify what would be expected.

HRSS – discussion of the definition of honest broker services and noted that the definition was currently under development and would be taken back to the National Information Governance Board in due course. However, they were working on defining the characteristics of an HB Service.

Function – this would involve matching and linking datasets. This would involve different types of pseudonymisation for different datasets.

Primarily, the pilots would serve to look at two types of research.

1. Observational – this would involve a patient-level dataset being linked then pseudonymised. It was noted that there would be small number suppression where cells contained 5 or under.

Members queried whether once the linkage and validation exercise had taken place, whether the identifiable data would be disposed of. It was confirmed that once the data items are linked and matched then the identifiable data items would be disposed of, however, it was noted that the original data items would remain within the Personal Demographics Service. Once linked and validated, an internal identifier that would not be based on NHS Number would be applied in order to pseudonymise the data. An additional layer of security would be added through applying a second level of pseudonymisation that would be study-specific. This approach had been taken so that two studies using the same data could not link their items together. Members noted that practically, and often within clinical teams, that people

2. Interventional – it was indicated that this would be in the context of fully consented clinical trials. The importance of this aspect was highlighted, along with the view that whilst 100% of data is collected, typically only 20% is used for clinical research, and therefore this represented an ideal opportunity to make greater use of relevant data. This would generally be carried out prospectively. The current situation - a dialogue would take place between the general practitioner and patient, and then the GP issues invitation to the patient, researcher would manually lok through records.

New process – a criteria for inclusion would be established. The HRSS would be asked to identify how many fell within the inclusion criteria through searching GP systems, PCTs and the General Practice Research database. The relevant GP would screen out those not fitting within the inclusion criteria, and the GP would write to the patient. This would therefore remove the need for the research facilitator and would render the process as becoming more automated.

Members queried whether the concept of an 'approved researcher' was proceeding. It was clarified that this would be, and this research facilitator would access non-electronic information and would be integrated into clinical teams.

Discussion focused upon the governance of the Pilots, and the Information Governance Framework, currently being discussed with the NIGB, and an Independent Audit Process would be in place to maintain effective governance.

Patient & Public Involvement – discussions focused upon coordination of a range of PPI activities, and notified that there had been a number of PPI groups both local and regional.
Clarified that only the minimum amount of data required for the purpose of the study would be used by the Programme. Once processed and the relevant information disclosed, then the original data would be deleted. It was confirmed that this data would be held for a maximum of 6 months prior to deletion. The outputs would be held for 25 years in line with Medical Research Council retention guidelines.

Committee provided with an update on PPI & Maria von Hildebrande who was working on producing a PPI handbook for patients and professionals.

Collection of empirical evidence for the 'consent for disclosure' issue.

Members queried the interplay between the National Analytical and Reporting Service (NARS) and the National Information Reporting Service (NIRS). It was confirmed that NARS would essentially be the replacement for Hospital Episode Statistics, and that NIRS would be carrying out a secondary uses function, for example, pseudonymisation methods.

2. Review of Regulations

The Department of Health is looking at the Health Service (Control of Patient Information) Regulations 2002 [SI 1438] ('the Regulations') with a view to introducing new Regulations in relation to Honest Broker services and for the Secondary Uses Service. Alongside this the Department has begun reviewing the current Regulations with a view to updating them and seeing if it is possible to reduce their scope.

At the September 2009 away day it was agreed in principle that the Regulations should be updated to accommodate changes in legislation, and specifically the provisions of the Human Tissue and Mental Capacity Acts. The purpose of this paper is to set out the nature and rationale for the proposed changes and to obtain the formal agreement of the ECC that these changes are recommended to the Board and then to the Secretary of State for Health.

The Committee is asked to:

Confirm the recommendations previously agreed in September 09 to update class 3 in the schedule to the Regulations in line with changes introduced by the Human Tissue Act 2004 (HTA) and Mental Capacity Act 2005 (MCA).

Purpose:

1. In relation to the Human Tissue Act - to facilitate linkage between data and tissue samples in de-identified form without consent where this is permitted by the Act.
2. In relation to the Mental Capacity Act - encompass within this class the identification of the relevant individuals (apart from the patient) from whom consent can be sought, in line with the provisions in these Acts.

Updating Class 3 in line with the Human Tissue Act

The proposed changes that were agreed in principle at the September 2009 meeting were:

1) that the Class be amended or a new class added to include processing of confidential patient information to facilitate the identification of relevant samples from existing holdings (collected before 1 September 2006) and for linkage between confidential patient information and tissue samples without consent, provided both are de-identified prior to linkage via a common pseudonym.

2) that the Class be amended or a new class added to include processing of confidential patient information to facilitate the identification of relevant samples from "new" collections (collected after 1 September 2006) for the living, and for linkage between confidential patient information and tissue samples without consent provided both are de-identified prior to linkage via a common pseudonym. **[NB Consent is now generally sought for the use of tissue from the living for research purposes, it is the linkage with data that remains an issue].**

3) With respect to new holdings from deceased persons, that the Class be amended to include processing of confidential patient information to facilitate the identification of relevant family members of, or individuals nominated by, the deceased person in order to seek their consent / assent for the use of tissue from and data relating to the deceased.

Updating Class 3 in line with the Mental Capacity Act

The proposed changes that were agreed, at least in principle, at the September 2009 meeting were:

1) That the Class be amended or a new class added to include processing of confidential patient information to facilitate the identification of relevant family members or individuals nominated by the person lacking capacity to consent to the research (in line with the

provisions of the MCA) in order that their assent/ proxy consent can be sought on behalf of the incapacitated individual.

2) That clarification be provided as to whether lack of capacity is sufficient justification to permit the use of Section 251. This is in relation to patients lacking capacity to consent to the disclosure of confidential information or to the use of de-identified tissue (in line with the above) for research not involving their direct participation.

Impact of change

These changes will provide clarification and explicit support to the way in which applications involving tissue samples have been handled in practice. They are intended to work with the provisions of the Human Tissue Act rather than requiring changes to it. The benefits of these changes are that they facilitate research and provide a clearer framework for the combined use of data and tissue for research.

3. ASCEND

This ASCEND (**A S**tudy of **C**ardiovascular **E**vents i**N D**iabetes) application from the Clinical Trial Service Unit (CTSU) at the University of Oxford was for a randomised trial that aimed to assess the benefits and hazards of using low-dose aspirin and/or omega 3 fish oils for the prevention of heart attacks and strokes in people with diabetes. This application was originally provided with section 251 support in 2003 by the Patient Information Advisory Group (PIAG). This support was provided to permit the study team to receive information about people with diabetes in order to invite them to participate in the study. Details of potential participants would be obtained from hospital based registers and regional registers (e.g. retinopathy screening), and the study team would receive name, address, date of birth, gender, NHS Number, and GP name and address.

The Committee had previously assessed the ASCEND annual review in November 2009; at which time a small number of patient complaints had been received, and a concern over recruitment of the cohort had been raised by the British Medical Association in Wales. In assessing the annual review at that time, Members discussed a complaint where it appeared a letter had been received directly from ASCEND, rather than from the clinical care team with whom the patient would have had a relationship such as a GP or relevant hospital team. At the November meeting, Members had provided continuing approval to ASCEND, with the condition that the initial contact with potential participants would be via a clinician known to them. Following subsequent correspondence with the NIGB Office, a visit to explore this condition of approval took place on 29 January 2010.

Outcome

In discussing the annual review visit report, Members noted that patients were primarily invited to participate via a central recruitment process which involved the ASCEND team contacting relevant GPs. The GP would sift potential participants and confirm those who could be contacted. ASCEND would then check vital status on the Central Register prior to sending out the invitation information. The cover letter would be on NHS Trust headed paper with a scanned signature from the senior doctor responsible for the care of that patient, which would usually be the consultant diabetologist. It was for this central recruitment process that section 251 support was provided in 2003.

When originally providing approval, PIAG had also requested that ASCEND explore other ways of recruiting participants, in a way that did not require support under section 251. It was noted that ASCEND had attempted to meet this condition of approval through asking GP practices to run searches for eligible participants and for the practice to send out the invitations directly. The study team would provide the practices with generic invitation packs and a template covering letter which each practice could amend to address and use their own letterhead.

Members noted that there were a number of difficulties involved in this second approach; namely that the study team would be reliant upon the practice to send out the correct invitation and evidence was cited of not all practices including covering letters signed from the GP. It was agreed that this was the likely root cause of the patient complaint discussed at the November Committee meeting. Additionally, Members noted that the applicant was unable to monitor the response rates by this method as there was currently no mechanism by which to monitor how many of the invitations had been sent out.

In assessing the different recruitment methods, the Members agreed that the CTSU had taken significant steps to test other methods of recruitment that did not warrant section 251 support, and agreed that due to the nature of the study and the fact that recruitment was scheduled to finish in the Summer, that the central recruitment method was in line with the original PIAG condition of approval. Members appreciated the fact that ASCEND had engaged with the condition of approval and were of the view that this presented an opportunity for learning for other similar studies.

Members also discussed the issues that had arisen in Wales after GPs in Wales were asked by the CTSU to filter lists of patients obtained from the Wales Retinopathy Screening Programme database. The BMA had felt that the disclosure to the CTSU was inappropriate as patients being invited onto the study were in contact with services on at least an annual basis and they had considered that consent was feasible. The Committee were informed that this had effectively stopped recruitment in Wales. Members were conscious of the importance of completing this activity, and recommended that where GPs had returned filtered lists to the CTSU that the recruitment should proceed. Members also considered whether it would be appropriate for a letter from the NIGB be provided that could explain the support provided under the Regulations. This letter would also request the practices to return the lists to the CTSU to permit recruitment or request the practices to send out the letters to patients themselves. If this would be useful for completing ASCEND, then his letter will follow shortly and can be distributed to the relevant practices in Wales as CTSU sees fit.

In conclusion, I am pleased to inform you that the Committee agreed to provide continuing support to ASCEND until December 2010. As recruitment is scheduled to finish in the Summer, this should allow sufficient time to allow for the recruitment and to carry out the anonymisation of those who were invited to participate but did not respond to the invitation. Should you anticipate that there will be a delay to this timescale for completing ASCEND activities, then please let the NIGB Office know by 29 October 2010 so that the status of continuing approval can be assessed in time for the Committee meeting in December.

Finally, the Committee wished to extend their thanks for engaging with the PIAG condition of approval, and with the NIGB Office in the carrying out of their annual review visit.

4. NCCHD

This was an application that was originally approved by the Patient Information Advisory Group in 2004 to provide for a statistical database of NHS activity on children in Wales which would be used to support the NHS Wales Department, and other Government functions and organisations in Wales. This database would be used for a range of purposes including supporting clinical management and care of children, evaluation of the effectiveness of screening programmes, and supporting and monitoring improvements in public health. Its previous annual review took place in 2007.

In assessing this annual review, it is worth noting that the purpose of an annual review is to meet the requirements of the Health Service (Control of Patient Information) Regulations 2002 No. 1438. In summary, section 7 of these Regulations requires those in possession of confidential patient information, in line with the approval provided under section 251 of the NHS Act 2006, to review their approval with a view to ensuring the minimal amount of processing is carried out, reducing the identifiability as far as reasonably possible and to ensure the level of security is appropriate.

Members were provided with a number of documents, including an update against the original application, the minimum dataset, use of and pseudonymisation of patient identifiable fields, terms of reference for various groups, and your responses to NIGB Office queries.

Discussion

Members welcomed receiving this annual review and were unanimously of the view that the outputs from the database provided a valuable resource and that it fulfilled a number of functions of high public importance. In particular, Members noted that this dataset allowed for manipulation of a number of different ways to describe child health in Wales. This compared favourably to the current situation in England where the data is not collected in a single place, and therefore the NCCHD represented a highly successful centralised resource that facilitated a coherent number of activities. This was highly praised by the Committee. However, despite the many positive outputs of the dataset, Members did express concern over the overall governance arrangements and appropriate compliance to relevant legislation in the context of section 251 support. This was considered especially important in ensuring that this valuable dataset operated within a transparent and appropriate legal framework that was proportionate to any risks.

Members were also mindful of significant organisational change in Wales which had understandably impacted on issues of governance of the NCCHD. Based upon the documentation, Members were of the view that the governance structures appeared to be out of date. They additionally found that some documents referred to (e.g. Appendix 5) were not always present or that links to subsequent documents did not provide the required information. As such, Members requested that a clear and up to date organisational governance structure be provided in addition to the further request for information set out below.

While there were many positive aspects to the application, the Committee focused upon a number of fundamental issues of relevance to providing continuing support under section 251. For ease of reference, this letter will focus on the following:

1. Exit strategy
2. Progress on consent
3. Pseudonymisation as an exit strategy
4. Requirement for an opt-out mechanism
5. Patient and user involvement
6. Outcome and further actions
7. Conditions of approval

1. <u>Exit strategy</u>

Members were mindful that support under section 251 is meant to be a temporary measure with a defined exit strategy such as consent, pseudonymisation or specific support under Regulations, in order to move away from reliance upon the current class support. When originally presented in 2004, Members had agreed that it would be more appropriate for this activity to fall under specific regulations rather than class support due to its size, range of purposes and large amount of data flows. However, they were mindful that at the time, progress towards developing legislation to incorporate this activity was some time away and therefore it was reasonable to provide class support to the NCCHD. This class support continued and was reviewed in 2007 where it appeared that progress towards pseudonymisation had been made. No annual review had taken place in the interim period, therefore Members were of the view that further progress would have been made, where possible, in moving forwards with any of the other aspects of an exit strategy. Members understood that it while it would be likely that new Regulations would be developed to include the NCCHD, that due to the current situation the expectation was that this would not progress in the short term. As such, the Committee focused upon how Health Solutions Wales had moved forwards with ether consent or pseudonymisation since the last annual review.

2. Progress on Consent

Where pseudonymisation is not appropriate as an exit strategy, consent is also a suitable move away from section 251 support. Members assessed section (3 i) of the 2010 documentation, 'Consent issues,' and noted the point that the Child Health team had no direct contact with patients. Members did note that when the data is collected by Trusts via the Health Visitor's 10-day visit, that the information collected by the NCCHD would be discussed with the child's parent. Members were of the view that, as the parent would be in direct contact with the service, that this would represent an ideal opportunity to seek consent for the holding of data on the NCCHD as it appeared that the NCCHD would be discussed in any event with the primary caregiver. As such, Members were unclear as to why consent for the holding of data could not be obtained at this point as it would not involve an additional intervention and was an ideal opportunity.

Members understood the documentation stated that the dataset required complete coverage, however they were not clear by what was meant by "*it would be difficult and time consuming to handle the presentational aspects of trying to achieve a 100% patient consent based on a fully informed decision*". Members also noted the view given that incompleteness because of opt-outs would introduce bias and would not be in the public interest, however, they were not satisfied that these aspects had been fully explored and evidenced, and were therefore not persuaded at this point as currently presented. Based upon these issues cited above, Members requested articulation of any practical difficulties involved in carrying out a consent-based approach where feasible. Members understood that consent might not be feasible in all instances, but considered that they had not been provided with sufficient reasons of the difficulties involved in seeking consent in order to justify that consent would not be practicable.

Members also noted the comment at the end of this section and the view provided that pseudonymisation is currently seen as the more practical and workable solution. Members agreed that where consent would not be feasible, taking into account the comments made above, then pseudonymisation would be more appropriate and therefore their discussions moved onto this aspect.

3. Pseudonymisation as an exit strategy

At the 2007 annual review, Members noted there had been some progress towards pseudonymisation as evidenced in the table attached to the 2010 review. This document stated that in relation to NHS Number, name and postcode, that these had been pseudonymised. However, attachment 2 of the 2010 annual review appeared to provide a current status update where it was indicated that, for example, NHS Number of mother had not received complete coverage and therefore once completeness and accuracy is checked, that it would be possible to pseudonymise this field. Another example was date of birth where it stated that age could be derived. Based upon this documentation, it was not clear as to whether these actions had been made due to an element of ambiguity in phrasing.

Members raised a concern that they were unable to identify from the documentation whether there had been any further progress towards pseudonymisation since the 2007 annual review. It is a statutory requirement of the Regulations that applicants assess, at a maximum of 12 month intervals, whether they can reduce the identifiability of confidential patient information in their possession when section 251 support is provided. As such, Members would have expected to have seen further moves towards pseudonymisation in the interim period, and expressed disappointment that this had not occurred. As such, Members requested detailed clarification on what had been pseudonymised, and also exploration of what other identifiers could also be pseudonymised. This was particularly important to Members as consent was not in place.

4. Requirement for an opt-out mechanism

Members discussed the responses provided to the NIGB Office queries in relation to the right of opt-out. It is worth highlighting that regardless of whether section 251 support is provided, applicants are still required to comply with the principles of the Data Protection Act (DPA) 1998. This importance is highlighted as patients have a right to object to the use of their personal data in certain circumstances, and in not providing a means to opt-out of their data being included, that this is in effect breaching the sixth principle of the DPA. Additionally, in not providing the cohort with an opportunity to opt-out of the data inclusion, this has the practical effect of using section 251 support to override dissent by not providing the cohort the opportunity to register this. Whilst it is clear this is not an objective of the applicant, it is also a standard condition of approval that section 251 support cannot be used to override dissent. As such, Members were concerned that there was no current mechanism in place to provide for the right of opt-out.

Members were also mindful of this aspect as it was not clear from the documentation whether the cohort were aware of the types of information collected (e.g. Hepatitis B, smoking history, health conditions causing concern) and their extremely sensitive nature. As such, Members requested to be provided with a copy of the fair processing documentation provided to the cohort.

Members noted the reason for not providing a mechanism to opt-out was due to reasons of requiring full population coverage, and noted the illustration of the pilot work carried out with the National Public Health Service Wales. Members were not persuaded by the arguments made against the right of opt-out and made reference to the Cancer Registries who also have section 251 support. The Cancer Registries are nationally based and have a huge benefit for public health, however, they provide a right of opt-out in compliance with the DPA. In the interests of consistency and compliance with legislation, Members therefore requested that this aspect be significantly revisited to move forwards with implementing a right of opt-out. Any detailed practical issues with this approach should also be provided, however, Members emphasised that the purpose of implementing this requirement was to ensure compliance with current legislation for the processing of this data.

5. Patient and user involvement

In providing support under section 251, Members assess the degree of patient and public involvement and considered this to be a fundamental part of any application. Members assessed the progress made in section (j) of the annual review table and that in planning for the database, consideration had been given into how to involve parents and user groups. Subsequent queries from the NIGB Office generated the response that an Expert Group had been put in place with membership including professionals in the areas of public health, Welsh Assembly policy and midwifery. Members were of the view that this represented a fundamental misunderstanding of user involvement, as the expectation from the Committee had been that this would include parents from within the general cohort. Whilst the importance of having professionals sitting on the Expert Group was important, there appeared to be no inclusion of patients and Members were not clear as to why this was the case.

In order to aid clarity for further work carried out in this areas by the NCCHD, Members emphasised that in this context, a group on user involvement should actually involve patients from whom the data is generated, not just those responsible for the handling the data for output purposes. The Committee would look to see how input from these patients or patient groups had influenced the work of the NCCHD, and they could also be helpful in exploring elements of consent. As such, Members requested that patient involvement within the NCCHD should be fully revisited based upon the clarification provided above and a plan developed on how involving patients will be integrated into the future work of the NCCHD. You might find it helpful to review the report from INVOLVE 'Exploring Impact: public involvement in NHS, public health and social care research' http://www.invo.org.uk/pdfs/Involve_Exploring_Impactfinal28.10.09.pdf. Members also suggested contacting the Children's Commissioner in Wales to aid you in progression of this work, and/or to make contact with national children's groups.

6. Outcome

Members were keen to emphasise that they were highly supportive of the outputs of the NCCHD, however, in order to provide support they are under an obligation to ensure that the use of section 251 is justified; that consent is obtained or pseudonymised data used where practicable and efforts are made to move towards an exit from reliance upon section 251.

Members were of the strongly held view that there were fundamental concerns over this application as set out above, and balanced this against the importance of providing continuing support under section 251. As such, and primarily due to the importance of the NCCHD, Members felt that the public interest in the outputs of the NCCHD justified the decision to temporarily extend the approval for a period of 6 months. This period of 6 months has been given so as to allow Health Solutions Wales sufficient time to develop and submit a revised application that would take into account the concerns articulated above. The applicants are strongly encouraged to provide a detailed application that fully engages with the points made in this letter in order to ensure that support can continue.

As such, the Committee agreed to provide provisional support to the NCCHD under section 251 for a period of 6 months. This approval is subject to the following conditions of approval.

7. Conditions of approval

1. Provision of a fully revised and complete new application that sets out the current status, in all aspects, of the NCCHD (e.g. incorporating progress since 2007 and beyond). This differs from the previous method of providing an update against the original application. This should be submitted to the NIGB Office by **29 October 2010** so that it can be assessed by the Committee at its meeting on 01 December 2010.

2. In particular, the resubmitted application will explicitly need to address exit strategies. The Committee accepted that specific support via Regulations is the long-term solution from relying upon the current class support, however, this is unlikely to occur within the short-term, therefore the Committee require consent (where feasible) and pseudonymisation to be pursued.

    a. The resubmitted application should look at all of the data flows and identify where consent or pseudonymisation is the most appropriate way forward. It is recommended that you provide a sufficient level of detail here to enable the Committee to reach an informed decision. For each data flow in to the NCCHD, you should also articulate any practical difficulties involved in pursuing the relevant approach. You might also wish to trial a consent-based approach on a specific data stream and it would be helpful to understand any plans you might have on this aspect as the Committee is unlikely to accept blanket assertions that consent is unfeasible.

    b. In terms of setting out what has been pseudonymised, this should incorporate progress in 2007 and onwards from that period. The application indicated that many options had been considered but it was not clear if they had been pursued. The Committee would expect this to be clearly set out and if no further progress had been made, then details provided on how this would be pursued. Members suggested linking in with other organisations such as the University of Swansea in order to utilise their expertise in pseudonymisation techniques if progress had not already been made.

    c. The application should also incorporate, and develop, the responses provided in response to the NIGB Office queries, and ensure all relevant and appropriate documentation is clearly cross-referenced.

3. Members appreciated that the changing organisational structure meant there was a lack of clarity around the overall governance, therefore they requested the application contain details of the most up to date governance structure and details of the relevant structures as Members had not been persuaded that the information provided was current.

4. In line with the requirements of the Data Protection Act 1998, and particularly the sixth principle, Members were of the view that the cohort should be provided with an opportunity to express any dissent from inclusion of the dataset. The application should clearly address this point in depth, and also set out any concerns or issues with this approach. The application should also include a copy of the fair processing information provided to the cohort.

5. The application should also revisit the requested identifiers and data items used. This point was raised as in Appendix 3 where Members had been confused by some of the justifications provided for use of data. An example was the justification given for Cystic Fibrosis and Muscular Dystrophy was that it aimed at reducing the incidence of the conditions to nil, however, Members were of the understanding that there is currently no cure for these diseases and therefore queried the achievability of this justification.

6. Patient involvement to be developed utilising support from other relevant patient organisations, and a plan for this aspect to be submitted with the application.

7. Please note that if subsequent approval is provided at the 6-month review point, that the Committee will require a review to be submitted on a rolling annual basis. This is in line with section 7 (1) (d) of the Health Service (Control of Patient Information) Regulations 2002 which states that those in possession of confidential patient information must review at intervals not exceeding 12 months the need to process the information. Templates and guidance are available on the NIGB website.

Due to the undisputed need for the NCCHD to have continued support under section 251, and some of the significant issues raised above, please note that the Chair will be writing to NIGAG to inform them of the Committee decision.

5. NHS Information Centre (NHS IC) – Patient & Public Engagement

Context

In its meeting on 03 February 2010 meeting, the Committee provisionally approved three applications from the NHS IC: Project Sutton (MIDAS) (ECC 2-04(b)/2010), Hospital Episode Statistics (ECC 2-05(b)/2010) and the Central Register (ECC 2-04(c)/2010). Members had been of the view that patient engagement had been limited within previous NHS IC applications, and due to its authoritative status that more significant steps should be taken to progress this important aspect of approval under section 251. As a condition of the provisional approvals provided to these three applications, it had been requested that the NHS IC present the Committee with its approach to patient engagement, and this plan should cover the following aspects:

1. A specific plan on who would be approached
2. Timescales for the activities
3. How the overall activity would be managed

At this meeting, the Committee were provided with a covering letter summarising the proposals, a Summary of the Independent Advisory Group proposals, the project mandate, project plan timescales and the draft discussion document ‘A Plan for Patient Engagement at the NHS IC – Processing Patient Information.

Outcome

Members noted that the NHS IC had met with two Committee Members and the NIGB Office prior to the April Committee meeting in order to discuss implications of the proposed plan, and welcomed the engagement of the NHS IC on this aspect. Members also noted the relevant section in the paper on the implementation of the Independent Advisory Group and its impact on HES, CHRIS and MIDAS.

The Committee's discussions focused primarily on the Appendix B Project Mandate and proposed plan for patient engagement. Members welcomed this plan in principle and agreed that it appeared to represent a significant step forward in this important area. However, Members also emphasised that the role of lay persons in a governance group is different from that of a lay person involved in patient and public engagement, in that the latter requires the involvement of the patient perspective at an operational level. Members agreed that it would be essential to ensure that persons with sufficient expertise in this area are drawn upon to aid the NHS IC in implementing effective patient and public engagement.

Members discussed the suggested governance structure and in particular, the establishment of a Patient Reference Group. Members noted that as HES, MIDAS and the Central Register are long-established data collections, it was understood that these will form the initial focus of the Patient Reference Group. The Committee welcomed the statement that the NHS IC would provide details of this outcome of this initial consideration to the Committee.

As a whole, Members welcomed any further updates that would be provided as the project progressed, and in line with the suggestion made in the documentation, would welcome an update being provided to the Committee in its December 2010 meeting. This has been provisionally scheduled into the December agenda.

As such, I am pleased to inform you that the Committee were content with this proposed approach in principle, and that it was sufficient to meet the current condition of approval set down in relation to HES, the Central Register and Project Sutton (MIDAS). Outcome letters regarding these applications will shortly be issued as appropriate.

6. GMC guidance

"efforts to seek consent unsuccessful" – Members were of the view that this was ambiguous.

Members noted that those wishing to access confidential patient information without consent were not required to seek support under section 251. In such a case, the issue would be whether the medical research would be of sufficient weight in terms of the public interest so as to outweigh the breach of confidentiality. Members also considered there to be a Human Rights aspect in terms of right to privacy and family life that would need to be considered. Members were of the view that as section 251 support would be available, those disclosing the information would need to justify why section 251 support had not been requested.

Members were of the view that medical research might not a sufficient defence in itself, and therefore section 251 support would be required.

Members assessed the comment "incorporated into the healthcare team" and understood this to be a justification of disclosure of confidential patient information to those who would not normally be entitled to access the data. Members agreed that this broad statement appeared to misunderstand why access to information was normally restricted to those members of the healthcare team. Members emphasised that members of the healthcare team have access to confidential patient information as it is necessary to provide care and treatment to relevant patients. This access is given on an implied consent basis as by attending a healthcare service, the patient would reasonably expect their practitioner to access their information in

order to provide direct care and treatment. Members were of the view that access to confidential patient information for the purposes of medical research is for a secondary use purpose, for which there is likely to be no implied consent in place. As such, the statement as it currently stood appeared to legitimise access to patient information for medical research, where there is currently no legal basis such as consent or section 251 support in place.