Meeting held on Thursday 3rd February

Present

Members: Dr Andrew Harris (Chair), Mrs Pauline Brown, Dr Tony Calland, Dr Patrick Coyle, Dr Tricia Cresswell, Ms Stephanie Ellis, Professor Sir Denis Pereira Gray, Mr Michael Hake, Dr Colin Harper, Professor Julia Hippisley-Cox, Ms Sue Parroy, Dr Mark Taylor

In attendance: Dr Alan Doyle *(NIGB Director),* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Approvals Officer),* Ms Melanie Kingston *(Deputy Approvals Manager)*, Mr Sean Kirwan (Department of Health)

1. Welcome and apologies

The meeting was chaired by the vice-Chair, Professor Sir Denis Pereira Gray until item 2G, the Chair had given his apologies for items prior to this and chaired the meeting from item 2G onwards.

Apologies were received from Dr Mike Catchpole, Professor Carol Dezateux, Dr Fiona Douglas, Professor Jane Kaye and Mr Terence Wiseman

Conflicts of Interest

Julia Hippisley-Cox declared a conflict of interest in item 2B as she was employed by the applying organisation. She did not take part in the discussion of this item.

2 New applications for section 251 support

2a. UK Lung Cancer Screening (UKLS) trial [ECC 2-02(a)/2011]

This application from the University of Liverpool set out the purpose of piloting a randomised cancer screening trial. This aimed to provide an evidence base for the possible introduction of population screening for high risk patients with lung cancer.

Section 251 support was sought to permit access to patient identifiable data from Primary Care Trusts so as to ascertain eligibility and facilitate the sending of invitations by RADAR, a data management company for clinical trials, to the eligible population. In particular, access to NHS Number, name, GP registration, date of birth, address and postcode was requested.

Members agreed this was an important study that was scientifically sound and were mindful of the importance to facilitate the study. It was noted that there were large numbers involved and that only demographic information would be required for the purposes of section 251, and the methodology would not involve sifting of clinical data. It was also agreed that there was a high public interest in this activity taking place. As a whole, the Committee found this to be a clearly written application that had sought to address previous and ongoing concerns over security and confidentiality.

The Committee discussed that one of its key principles was that the initial contact with potential participants should be via someone ‘known’ to the patient, such as a GP or a hospital clinician

known to the patient, as this acts as a counter-balance to processing personal data under section 251. However, in this specific instance and mainly due to the large numbers involved of 4,200, members agreed that an approach via GPs would add a further layer of complexity and would not be proportionate due to these large numbers, and therefore agreed that it would be appropriate for the letter to be signed by the Director of Public Health. Members subsequently reviewed the invitation to participate letter and noted that although it would be signed by the Director of Public Health (DPH), the address details given were that of the clinical trials unit in Liverpool. This was felt to be unclear and in line with this, members were of the view that if the letter was to come from the DPH, then the letter as a whole should be on the appropriate letter-headed paper originating from the DPH. The research team details should appear only in the response envelope, or be referenced as a point of contact within the body of the invitation letter.

Additionally, it was queried whether the DPH had approved the content of the letter as previous experience in similar situations had shown that the DPH often amended the content of the letter on the basis it would be addressed by them. Members therefore were strongly of the view that the letter should be amended so that it would be signed by the DPH and be on their letter headed paper.

Members also noted that the invitation letter stated within the fourth paragraph that "*you have been randomly selected from individuals aged 50 to 75 years of age from your local Primary Care Trusts*". A point was raised that it would be important for the participant to be aware that they had been randomly selected and that the selection had not taken place using clinical factors. Members therefore requested consideration to be given to amending this aspect of the letter to provide further clarity to the participant from the outset of the random nature of the invitation, as the participant would have to read the letter in detail to be aware of this.

Members requested that the response to achieving compliance with the first principle of the Data Protection Act be amended. The 'fair processing' principle would be met through providing the cohort information on the proposed use of personal information, and members were of the view that further efforts could be made such as via the use of posters being provided at a local level. In line with this, members agreed that a revised response should be provided from the applicant which showed how compliance would be met.

In terms of the scope for which section 251 support would be required, it was noted that there would be a pilot and a main phase, the Committee focused solely upon the pilot phase. However, the Committee were mindful that it would be likely that the main phase would follow. As an incidental point, the Committee noted that the NHS was currently undergoing significant organisational change, and for the main activity, it would be likely that the current structures relied upon might no longer be in place, therefore the methods currently described would be likely to require alteration to reflect the new structures.

Based upon the considerations above and in particular, the high public interest in the pilot phase going ahead, the Committee agreed to recommend provisional support under section 251 to this study. This provisional approval was subject to the following request for clarification:

1. Within the wording of the consent form, it was noted that it stated regulatory authorities would check the information. The applicant was asked which regulatory authorities were referred to here, and what would be their reasons for access

Final approval under section 251 support would be provided with the following conditions:

1. Amendment of the invitation letter that covered:

    a. Emphasis of the random nature of the invitation, and detailed that selection had not been based on clinical factors

b. Amendment of the invitation letter to clearly show it was addressed from the Director of Public Health with appropriate letter heading, and with the research team contact details contained within the body of the letter as necessary.

2. Amendment of the response to the first principle of the Data Protection Act 1998 to reflect fair processing requirements, including placing posters in patient waiting areas describing the study and how people can opt out.

3. That the provisional approval related to the pilot phase only.

Action: NIGB Office to notify the applicant of Committee decision.

2b. ROTEM – Coagulopathy in Sepsis [ECC 2-02(b)/2011]

Julia Hippisley-Cox left the room for this agenda item.

This application from the University of Nottingham set out the purpose of determining whether clinicians should be using alternative assays to diagnose and evaluate the extent of bleeding disorders in critically ill patients on the basis they were more accurate and detected problems earlier than currently available tests.

Section 251 support was requested to enable legitimate access to medical records by the research team in order to enable identification of suitable participants. As the study also involved taking blood samples from unconscious patients, consent would be sought from patients' relatives or next of kin for inclusion into the study. Retrospective fully informed consent would then be obtained once the patient regained consciousness. If the patient died or remained too unwell to give consent then the next of kin consent would be considered sufficient.

The Committee was largely supportive of this study and recognised it was looking at a rare condition with a high mortality rate and that it would be in the public interest to carry it out. They noted that the patient would be undergoing blood tests for routine clinical care at the same time as the additional test taken for the study, however in light of the public interest in the study they agreed that the additional test would be proportionate.

Members expressed concern at the use of the term 'implied consent' throughout the application as they considered this to be misleading. Implied consent was generally inferred from a person's action so it could not be assumed if they were unconscious. For the purposes of the study, members believed that the term third party assent would be more appropriate as a representative would give assent on behalf of the patient.

Members noted that the responses to the Data Protection Principles required further detail, especially those relating to the provision of patient information and allowing the right to opt out of the use of data and how dissent would be respected. Members noted that the leaflet provided contained some medical terminology which would not necessarily be easy for a lay person to understand; it was discussed that the applicant could approach patient groups in order to make this more understandable to a range of audiences.

The Committee noted that due to the nature of the study both the Human Tissue Act and the Mental Capacity Act would have to be adhered to. Whilst this particular part of the study was out with the Committee's remit they requested that the applicant be informed that they would need to ensure compliance. The Committee also clarified that any approval under section 251 would relate to the collection of data only.

In conclusion members agreed to provide provisional approval under section 251 to allow researchers to screen notes and approach next of kin; this was subject to the following request for clarification:

1. When the patient's next of kin are not present at the unit the applicant should detail how they intend to seek their assent.

Approval under section 251 would be subject to the following condition of approval:

1. Further detail to be provided around the Data Protection Act principles to show how the applicant intended to comply with the requirements.

Action: NIGB Office to inform applicant of Committee decision.

2c. PARAMEDIC: Prehospital Randomised Assessment of a Mechanical compression Device in Cardiac arrest [ECC 2-02(c)/2011]

This application from the University of Warwick set out the intent to carry out an assessment of the Lund University Cardiopulmonary Assistance System (LUCAS) device used by paramedics during cardiopulmonary resuscitation (CPR) for patients who suffer out of hospital cardiac arrest, in order to assess the survival rate of patients in comparison to standard manual compression.

Section 251 support was sought to permit the transfer of patient identifiable information to the research team so that they could send out initial contact letters. Section 251 support was also sought to permit the flagging of patients on the Central Register so as to ascertain survival status. In particular, access to the following information was requested: name, NHS Number, date of birth, date of death, postcode and telephone number. For analysis purposes it was proposed that the following would be retained, date of birth, date of death and gender.

The Committee noted that the cohort of patients would include many people in an emergency situation and therefore not seeking consent could be considered reasonable. It was also agreed that there was a significant public interest in this activity taking place.

Members noted that originally the trial had been designed so that patient identifiable data would not be transferred from the ambulance services to the trial coordinating centre without consent. Previously the ambulance service would identify the surviving participants, would act as the initial contact in informing the patient about potential participation and would seek permission for the patient to be contacted by the researcher. However, the application detailed that problems had arisen using this approach whereby the ambulance service had found it difficult to identify survival status. These issues around incorrect identification of the patient's status and therefore an ultimate lack of contact had led to loss in participation. The Committee was sympathetic to this situation and agreed that the applicant had provided an evidence based approach to justify this change in methodology.

Members reviewed the invitation letter and queried under which letter heading the letter would be issued. This was considered important as one of the Committee's key principles was that initial contact with potential participants should be via someone 'known' to the patient, such as a GP or a hospital clinician, as this acts as a counter-balance to processing personal data under section 251. In line with this, Members requested confirmation that the letter would be issued on Trust letter-headed paper.

Members also reviewed the list of required data items and could not locate information to explain why telephone number had been requested. It was understood that the research team would write to the patient, however, the Committee could not identify a clear justification for this information being provided, and therefore did not agree to provide section 251 support for the use of telephone number.

Based upon the considerations above, the Committee agreed to recommend provisional support under section 251 to this study. This would be subject to the following request for clarification:

1. Clarification over how long patient identifiable information would be retained. This should be the minimum amount of time necessary before the information could be anonymised or pseudonymised.

The provisional approval would be subject to the following conditions of approval:

Conditions of Approval

1. Amendment of the invitation letter to appear it had originated from the ambulance service and to be issued on trust headed paper.

2. That the provisional approval would not cover access to the patient's telephone number.

Action: NIGB Office to notify applicant of Committee decision.

2d. European Surgical Outcomes Study (EUSOS) [ECC 2-02(d)/2010]

This application from Southampton University Hospital NHS Trust set out details of a European study and in particular, sought to establish the in-house mortality rate for patients undergoing major general surgery in Europe through assessment within 57 United Kingdom sites. It was noted that this activity would take place over a seven-day period in April 2011.

Section 251 support was sought in order to permit the transfer of patient identifiable data to the research team to enable the data collection from medical records, and to facilitate the sending of invitation letters. In particular, access was sought to name, hospital ID, date of birth and death, and to gender for analysis purposes.

Members agreed that this was an important study with a public interest, and that the outcomes would be important to provide a comparative answer to the issue being investigated. Members noted that potential participants would be identified by the local clinical care teams which would not involve a breach of confidentiality; therefore this specific aspect was outside the scope of section 251. Members also focused on the statement in the application that it was considered crucial for a complete dataset of consecutive eligible patients undergoing major general surgery at each hospital to be collated.

The Committee looked for sufficient evidence that the provisions of the Data Protection Act (DPA) 1998 were being complied with. The Committee assessed whether the data would be used fairly and lawfully in line with the DPA, the sixth principle in particular referred to the right of data subjects when their personal data was being processed. The Committee were unable to locate information in the application that the data subjects would be made aware that their data would be used for this purpose, nor any way in which they could express consent or dissent. The Committee reiterated that having section 251 in place would not override this fair processing requirement contained within the DPA, and therefore this would need to be addressed.

As section 251 could only be used as a last resort, members discussed whether sufficient justification had been provided as to why anonymised data would not be sufficient for the specified purposes, and whether a consent-based approach would not be suitable.

Within the application the estimated time needed to take consent was stated to be two hours per patient; this was reviewed in the light of arrangements in other research studies and appeared to be extensive. In addition the Committee noted the fact that the patients selected for the research would all be undergoing surgery and would therefore be going through a separate consent

process. The Committee were not clear that the potential for taking consent at the same time or soon after the first consent process had been fully explored, and were of the view that the consent process for this activity did not need to be overly burdensome.

The Committee noted the aspiration of the researchers to obtain a consecutive series and the intention to have as complete a sample as possible. However, the Committee balanced this hope against the need to respect the provisions of the DPA and the reasonable right of data subjects to know what their data are being used for, and to register consent or dissent.

In light of these considerations, the Committee unanimously decided that a recommendation of section 251 support would not be appropriate as there appeared to be a reasonably practicable alternative to using section 251 via a consent-based approach.

Action: NIGB Office to notify applicant of Committee decision.

2e. Patient outcomes in suspected acute coronary syndromes (ECC 2-02(e)/2011

This application from Stockport NHS Foundation Trust set out to estimate the unmet need for myocardial infarction and unstable angina patients who should be referred for angiographies and other interventions.

Section 251 support was sought to facilitate access to medical records from an original cohort of audited patients (a total of 718), and death certificates available from the Medical Research Information Service. In particular, the application requested access to name, NHS Number, hospital ID, date of birth and postcode for linkage/validation purposes, and date of birth, date of death, gender and ethnicity for analysis purposes.

Members noted that this activity had a legitimate public interest and agreed that it would be important for the activity to take place. However, the Committee was unclear on whether this activity was research or audit. While the data collected on the original cohort might have been for the purpose of audit, this current study appeared to indicate that it could be research. In line with this, the Committee requested confirmation from a research ethics committee as to whether this specific activity was considered to be research or audit. Members also requested sight of any correspondence from the REC in relation to the original audit being classed as non-research. This was important for the Committee as under its statutory remit, it would require this assurance.

The Committee highlighted that section 251 support could only be recommended where clear evidence was provided that consent would not be practicable, and that pseudonymised data would not be sufficient. Members were unable to locate clear justification as to why consent would not be feasible where the patient was alive, and did not identify evidence to support the view that it would be disproportionate to seek consent. They were also of the view that the participants would be likely to look favourably upon activities seeking to evaluate their care.

The Committee noted that they did not have authority to alter the terms of the Data Protection Act (DPA) 1998 and were required to ensure that its provisions would be complied with when seeking to recommend support under section 251. From the review of the documentation, the Committee understood that the data subjects would not have any knowledge that their data would be processed for the stated purpose, and therefore no practical way in which to indicate consent or dissent. Based upon these considerations, the Committee were of the view that consent for living patients would be a viable option, and where there appeared to be a reasonably practicable alternative, section 251 support could not be recommended.

The Committee were therefore unable to recommend support to the whole activity, however, where the patient was dead it was agreed to recommend support under section 251 for access to death certificates via MRIS. As it appeared that consent would be feasible for those who were alive, section 251 support was not recommended for these living patients. Before approval could be recommended, some clarifications were requested:

Request for clarification:

1. Confirmation over whether a REC opinion would be sought regarding the specific activity.

2. A copy of any available correspondence from the REC in relation to the original cohort should be forwarded to the NIGB Office. This should confirm that the study was an audit and did not require ethical review

Any approval would be subject to the following conditions of approval:

1. Section 251 support would be provided to permit access to death data from MRIS in relation to deceased patients – for those patients who are alive, consent should be sought.

Action: NIGB Office to notify applicant of Committee decision.

2f. British Childhood Cancer Survivor Study (BCCSS) ECC 2-02(f)/2011

This application from the University of Birmingham described the establishment of a population-based database relating to a cohort of 40,000 individuals diagnosed with cancer when aged under 15 years, between 1940 – 2010 inclusive, and surviving at least five years from diagnosis. This database was established for the purpose of identifying risks of fatal and non-fatal serious adverse health outcomes following cancer treatment in childhood.

Section 251 support was requested to allow an extension to include an additional sub-cohort of 22,000 individuals, and to permit linkages between HES, PEDW, Scottish datasets and MINAP. In particular, the application requested access to name, NHS Number, hospital ID, GP registration, date of birth, date of death, postcode and clinical information. Date of birth, date of death, postcode, gender and ethnicity were also required for analysis purpose

Members noted that the reason for seeking support under section 251 was to extend the existing cohort and agreed that this was an important study that would provide answers to questions in the public interest. It was also noted that this would provide a unique data source that would be a valuable research repository. The Committee was supportive as a whole to this application, noted the reference to the previous TYACCS [ECC 3-03 (d)/2010] application and agreed that they were keen to support the application in principle. However, further clarity was requested on certain aspects in order to be clear where section 251 would be applicable and what it would cover.

Requests for clarification:

1. Members were unclear on the precise data flows; which data items would be required for linkage purposes, and what would flow back to the BCCSS. As such, the Committee requested that the applicant set out in detail the flows of identifiable data and linkage aspects.

2. Members also sought clarity on the data that was currently held, and data which was held in a de-identified format. The query arose in relation to the separation of identifiable data from the information held for research purposes. Further clarity was sought on what was held in each.

3. In line with the point above, Members noted that access was to be given to pseudonymised data for research purposes and sought clarity over what data was necessary for the applicant's own analysis and what was necessary for third parties.

4. Clarity was requested on how long identifiable data would be retained

5. Further clarity was sought on how notification of dissent would be managed

6. In terms of compliance with the Data Protection Act, further information was requested on how fair processing information would be provided to the cohort.

7. Questions were raised over the onward disclosure of data and specifically the controls, linkages and undertakings from those in receipt of the data, and assurances were sought over this.

8. Members queried whether this activity could be placed under the banner of the cancer registries, in terms of adhering to their governance arrangements as these have already been approved in line with their statutory approval under section 251. This would also aid in providing a coherent national approach to the repository of cancer information. Significant consideration should be given to this aspect as the Committee noted that they would expect to see any further similar studies being placed under the registries governance arrangements

9. Views were expressed that patient involvement could be strengthened, and requested that the applicant provide some commitment to this.

Until clarification on these points was received members could not make a decision on this application. It was agreed that once clarification was received then it could be processed outside of the Committee meeting by members who had reviewed the application originally.

Action: NIGB Office to notify applicant of Committee decision.

2g. Sonovue [ECC 2-02(g)/2011]

This application, made by Premier Research on behalf of the applicant, set out the purpose of identifying and seeking evidence to support the use of Sonovue as a contrast agent for echocardiography.

Section 251 support was requested to facilitate access to death /survival status data in relation to patients between 01 September 2001 and 31 May 2010, and the subsequent transfer of death notifications to Bracco. In particular, the application requested access to date of death for both linkage and analysis purposes, and ethnicity for analysis purposes.

Members agreed that the purpose appeared to be valid and reasonable, and were supportive in principle of the activity.

However, the Committee considered the application to have some inconsistencies within it, which lead to confusion over precise arrangements. For example, in the application form, there was some indication that consent would be sought, in particular for the sponsor to review medical records, however, the Committee was unclear as to the precise arrangements and at what point, if any, consent would be sought. The Committee noted that the applicant had provided the REC response to this activity which had deemed it unethical to get consent from next of kin.

Therefore whilst the Committee were supportive of the application in principle, due to a number of aspects that required clarification, it was agreed that clarity would be sought, and the responses would be returned to the Chair for a final decision:

Request for clarification:

1. Confirmation over who would be extracting the relevant data from the medical records and whether this would be the clinical care team within the trust.

2. Whether there would be any intention for the sponsor to review any of the clinical records, if so, details were requested over what arrangements would be in place to manage this.

3. It was noted that principles 1 and 6 of the DPA response section had not been completed sufficiently. Whilst the DPA relates to the living, the Committee reiterated that the common law duty of confidentiality continued past death, and under section 251, decisions taken cannot be inconsistent with the DPA. The Committee therefore requested that considered responses be provided to demonstrate how the applicant would be compliant with these principles.

4. Clarification over whom the information would be shared with and also the jurisdictions the information would be transferred to.

5. Where consent was referred to within the application, the applicant was requested to clarify in what situations consent would be sought and what this would cover

6. If consent was not intended to be sought, then such references should be removed from the application form.

Action: NIGB Office to notify applicant of Committee decision.

3. Any other business

<u>The Academy of Medical Sciences review "A new pathway for the regulation and governance of health research"</u>

In the spring of 2010 the government asked the Academy of Medical Sciences to conduct a review of the 'regulation and governance of health research involving human participants, their tissue or their data'. NIGB submitted written and verbal evidence to the Committee chaired by Sir Michael Rawlins on two occasions and meetings were held with both the Chairs of NIGB and ECC in order to exchange views. The report recommended the establishment of a Health Research Regulatory Body (which had been agreed in the Arms Length Body Review published in May 2010) and incorporation of Section 251 research approvals into this organisation when established in order to streamline the research approvals processes.

Members discussed the content of the report which had been published in January. Members were mindful that any response to the review would need to be formulated in collaboration with NIGB members. They therefore agreed that ECC members' comments around the relevant points in the report should be presented to the NIGB Board and that they would then decide if a response would be appropriate.

Members noted that this was an extremely important document and suggested that they would regard a response to the review to be highly appropriate.

In reviewing the report members were particularly mindful of the rights of patients and the level of trust that patients put in the NHS. It was noted that there would be extreme detriment in damaging this trust. Members were concerned therefore at the lack of reference to the patients' view or the issue of conserving trust in the NHS whilst facilitating research. The reference to the most recent consultation exercise into patients' views around the use of their data in research was welcome, however it reflected that patients and the public were supportive of research but also that they expected to be asked for their permission to disclose their data to researchers. Members noted that whilst they were encouraging of the attempts to further facilitate research the issue of trust was deemed extremely important in balance with this.

Additionally members noted that the report advocated the inclusion of researchers into the clinical care team of the patients, where in reality researchers would only rarely be providing clinical care. Members wished to reiterate their view that whilst some clinicians who were also researchers could

be considered part of the clinical care team, the suggestion that those who required access to patient identifiable data purely for research purposes were part of the clinical care team was an artificial one. The Committee considered that patients would not regard such persons as being part of their clinical care team.

Moreover the Committee agreed that whilst it was supportive that the proposed research regulator would bring together expertise it would need to ensure it retained the expertise that had been developed, not only within the ECC but also within other bodies which provided advice around tissue, in vitro fertilisation and embryology research. Lay membership was also considered of importance in order to retain the accountability and views of the public in decisions.

The Committee noted that there although it was proposed that section 251 approvals in relation to research would be taken on by the new research regulator it was less certain how non-research studies, such as national audit or service evaluation, would be processed in relation to access to patient confidential data without consent. This would require an appropriate strategy as the common law duty of confidentiality would still be applicable, and it was these specific areas that involved the largest collections and use of patient identifiable information, typically without consent. The Committee noted that suitable control around national databases and data flows would be particularly important.

In conclusion the Committee welcomed some of the reports proposals but wished to reiterate the vital nature of an independent and transparent role in ensuring the appropriate balance between patient confidentiality and the public interest. It would be essential for this to be maintained with the appropriate accountability and input from relevant expertise and lay members.

Action: NIGB Office to report Committee's views to the February NIGB meeting. Further detail of NIGB response to be included within February NIGB meeting minutes.