NHS
Health Research Authority

**Minutes of the meeting of the Confidentiality Advisory Group**

**01 December 2016, 10am at Mercure Piccadilly Hotel**

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**Present:**

| Name | Capacity |
|---|---|
| Dr Mark Taylor (Chair) | |
| Dr Patrick Coyle (Vice Chair) | |
| Dr Murat Soncul (Alternate Vice Chair) | |
| Dr Martin Andrew | |
| Professor Barry Evans | |
| Ms Hannah Chambers | Lay |
| Dr Lorna Fraser | |
| Ms Kim Kingan | |
| Dr Rachel Knowles | |
| Dr Harvey Marcovitch | |
| Mr David Smallacombe | Lay |

**Also in attendance:**

| Name | Position (or reason for attending) |
|---|---|
| Ms Natasha Dunkley | Head of Confidentiality Advice Service, HRA |
| Ms Kathryn Murray | Senior Confidentiality Advisor, HRA |
| Ms Laura Frisby | Senior Confidentiality Advisor, HRA |
| Ms Rachel Heron | Confidentiality Advisor, HRA (Items 1 – 3 inclusive) |

## 1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies

No apologies were received for this meeting.

Declarations of Interest

Dr Harvey Marcovitch declared an interest in respect of application 16/CAG/0155 (Agenda Item 5a). Dr Marcovitch declared that he had a historic professional relationship with the Chief Investigator named on the study and was also currently Honorary Fellow at the RCPCH, where the Chief Investigator is President. The Committee agreed that Dr Marcovitch could remain during discussions but would not participate in the CAG consideration and recommendation.

## 2. APPROVAL DECISIONS

The following was shared with the CAG for information.

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the 31 October 2016 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the 31 October 2016 meeting applications.

## 3. ITEMS FOR CONSIDERATION

### a) Public and Patient Involvement Event – 22 February 2016

A discussion took place around the planning and development of the Public and Patient Involvement event, which was scheduled to take place in February 2017. A number of comments and suggestions were put forward by Members which the Chair agreed to follow-up in conjunction with the officials and members of the CAT.

### b) NHS Digital – A New Approach to Working with NHS Digital

The Chair provided an overview on discussions which had been held to date with colleagues within NHS Digital around formalising ways of working to enable CAG to discharge its statutory responsibilities as defined in the Care Act 2014. It was highlighted that previously the CAG had originally taken the position that they would not be able to advise until the Data Dissemination Framework had been sufficiently developed to enable 'edge' cases to be assessed. However, it had become clear over time that the Framework was not likely to move forwards with a clear timescale. The Chair noted that the initial correspondence from Dr Severs had been received that had set out a possible interim working arrangement. This had been assessed in conjunction with the HRA and the Chair had iterated a response that sought to provide clarity on potential future working arrangements. This initial proposal and developed counter-proposal had been shared with all Members via the Chair's report and was discussed at the meeting.

The Chair welcomed comments and queries from Members. It was queried at which stage in the guidance allowed provision for the CAG to proactively offer advice to NHS Digital as this did not appear immediately clear. The Chair advised that this was accounted for in stage one of the proposed arrangements and clarified that the reference to HRA within this step was intended to mean members of the CAT as they were well placed, due to feedback from applicants and general organisational queries, to reactively identify those areas impacting on researchers in relation to dissemination.

Members discussed transparency implications at step two and it was queried whether documenting the discussions would be appropriate as currently it was unclear what outputs would arise from this step as there was no information in the public domain, and if CAG was advising under the Care Act, then this should be documented. It was agreed that separate notes would need to be published in relation to any discussions with/advice provided to NHS Digital, in to enable a clear distinction to be made between guidance given under the Care Act 2014. It was noted that there had already been anecdotal comment from third parties that CAG was currently advising NHS Digital. The standard CAG minutes provide advice given under the COPI Regulations therefore including information on NHS Digital within the existing minutes would prove difficult to locate by an interested reader. However, it was noted that there may be occasion when it is appropriate for the advice to be referenced under both the Care Act and the COPI Regulations, for example if the guidance was

considered by CAG itself. Members also queried when a response would be due form NHS Digital, and discussed the longer-term aim of solidifying the relationship via a memorandum of understanding. A concern was raised that there was not a clear sense of timescales and progression in terms of advice requests or move to the longer-term plan, and I was important, in order for CAG to effectively discharge its function, for these timescales to be established to move forwards.

Members agreed that issues of principle must be brought before the Committee as a whole and not presented to individuals. It was further commented that the informal route defined in the document posed risks for the CAG and potentially left the individual involved in the informal discussions vulnerable to criticism should the formal agreed pathway not follow that which was suggested informally. The Committee agreed that the best way forward would bring all queries to a physical CAG meeting to enable discussions to be formally documented.

In terms of keeping the CAG fully updated with any discussions that take place outside the formal meeting, as an interim step it was agreed that while the Chair Report provided a very high-level summary, in order for CAG to have full sight of any relevant issues that a separate report, similar to the existing Office Report, would be provided once this item had been discussed with members, to commence early 2017. Members agreed that this was an essential step to support transparency, especially as there were no clear processes yet in place. It was also noted that there would need to be a specific update on the website in relation to the Care Act 2014 role as soon as NHS Digital responded positively to the revised proposal.

The Committee agreed that it would become critical for a substantive response to be provided as soon as possible from NHS digital in order to ensure progression. Should a response to the most recent correspondence not be received ahead of the next CAG meeting, which was scheduled for 12 January 2017 a follow-up letter would be sent outlining the above agreed intentions and points raised, to provide NHS Digital with an overview of the agreed interim process and to ensure mutual agreement.

## 4. NEW APPLICATIONS – Non-research

### a) 16/CAG/0152 – National Bone and Joint Infection Registry

Purpose of application

This application set out the purpose of developing a national registry for Bone and Joint Infections in the UK intended to be used for audit and service evaluations. The project seeks to capture data about affected patients and the care they receive for bone and joint infections. The registry aims to enable a robust understanding of the current care pathways and the most effective treatments using comparisons between different units and the patient outcomes they achieve. The registry will record all relevant information on native and device related bone and joint infections. Patients, of all ages, with diagnoses of long bone osteomyelitis, native joint septic arthritis, prosthetic joint infection of any joint replacement and spinal infections will be included in the registry. Information held by the Trusts treating these patients will be transferred to the registry database, to be held by Northumbria Healthcare NHS Trust and which can be linked to other datasets

The application outlined the registries purpose as being used in preventative medicine. This would involve informing preventative strategies in avoiding chronic infection, medical diagnosis and to aid in better understanding of how care is currently delivered to identify models of best practice to improve outcomes.

A recommendation for class 1, 4 and 5 support was requested to cover the relevant activities specified in the application.

Confidential patient information requested

Access was requested to patient data held by the treating Trusts to be transferred to the registry database to enable linkage with other datasets. The main purpose for linkage is to match any records for patients treated at multiple sites for the same or different episodes of infection.

Access was requested to the following identifiers:

- Age
- Sex
- Data of birth
- NHS Number
- Date of death
- Ethnicity
- Hospital Unit Identifier
- Date of admission
- Date and time of discharge.

Patient identifiable information is required to:

- Link registry records with HES data that relate to previous surgery that patients have received at the infection site and/or any previous treatment for infection at that site
- Linking with the National Joint Registry and National Hip Fracture Database for information about previous surgeries

**Confidentiality Advisory Group advice**

Public interest

CAG agreed that this activity had a medical purpose and felt this to be an area of strong clinical importance. However, in assessing the public interest, members were unclear on the prevalence of infection. It was therefore indicated that a level of quantitative information should be provided to help demonstrate the prevalence and in consequence, the public interest in the establishment of this Registry.

Members also queried how the Registry would ensure comprehensive coverage, as this was an important public interest consideration in seeking to process patient information without consent. It was noted that support, if provided, could only extend to data generated within England and Wales. It was unclear to members how data from Scotland and Northern Ireland would be obtained therefore further information was requested on how that data would be accessed.

Due to the contradictory language used throughout the application, members were unclear as to whether the application was research or non-research and further clarification is sought from the applicant.

Members discussed the commercial sponsorship arrangements for the registry and it was noted that there was potential for commercial influence on the use of any future findings, clarification was requested as to the registry being free to publish data without commercial censorship and clarification that the registry will not be used as a marketing tool.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The applicants articulated that many of the groups of patients affected would not have the capacity to consent as the clinical syndrome found with any infection would prevent patients giving informed consent due to sepsis, delirium/confusion and any pre-existing cognitive impairment. The applicants felt it not practicable to involve only those with capacity to consent due to creating an unrepresentative sample in which significant groups would be excluded and believe the value of the dataset comes from data collection of the entire affected population.

Members agreed that most patients will be acutely unwell and some will be chronically ill, however members sought clarification on the expected percentage that may not be able to provide consent.

Members were also concerned that too much emphasis had been placed on patients lacking capacity as a justification for the application, and advised that support could typically not be provided for reasons of lack of capacity. It was advised that the applicant should consider the provisions of the Mental Capacity Act, as support if provided, does not override any other legal provisions.

- Use of anonymised/pseudonymised data

The application specified that using anonymised information was not practicable as it would prevent linkage to other datasets and may lead to a significant risk of duplication of records. Members agreed this appeared appropriate.

Patient notification and objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

A patient leaflet had been created with the support and advice of a patient liaison group which outlined the information being collected, the purpose of the registry and stated that patients can request for their information to be removed, highlighting a weblink in the document for patients to visit to 'opt out'. Members felt that the language used in the leaflet was not entirely appropriate for the audience and warranted significant change. For example, members advised that changes should be made to the following:

- Amend 'Commercial providers, particularly those who are sponsoring the project, may request access to data' as it had already been stated that no one will have access,
- The leaflet must outline what data is being collected,
- Provide further information regarding the opportunity to 'opt out' in addition to providing a link to the website,
- Reword the section 'About Us' using appropriate lay language, doctor rather than physician as this accurately reflects English healthcare.

Justification of identifiers

The application stated in order to undertake the linkages that full date of birth will be used. CAG queried if identifiability could be reduced to age at episode.

The application outlined the patient identifiers to be gathered, however it was noted that the addition of patient name was listed in the dataflow diagram which was not outlined in the application. Members requested further clarification as to whether name was required, and if so, a clear justification provided.

Members also queried the role of Dendrite, and felt that their role was unclear in terms of what information Dendrite would be receiving and if it would be identifiable. A clear description of this was therefore requested.

Patient and Public Involvement

CAG noted the described level of patient engagement, however, members expressed some level of concern as to how independent the events were due to medical staff supervision/intervention. Members asked for clarification on how these events remained independent and genuinely of the patient voice.

Additional points

Members noted that three classes of support had been indicated. Members emphasised that the high level activities set out within the classes of support related only to the specific data flows listed and detailed within the application, and should not be applied more broadly.

**Confidentiality Advisory Group advice conclusion**

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

**Further information required**

In order to provide a recommendation to the decision-maker, the CAG have requested that the following clarifications be responded to in a formal response through a detailed letter. Once complete responses are received, these will be considered at the next available CAG meeting at which point a recommendation will be provided to the Secretary of State for Health.

In order to resubmit, please provide a formal response to all of the points raised, indicating clearly where the points raised have been addressed and clearly highlighting relevant supporting documentation.

1. Please provide clarification of which data items Dendrite is receiving and clarify whether Dendrite is receiving any identifiable data items

2. Provide clarification as to whether the registry is intended to include data generated only in England and Wales or the whole of the UK. Please be advised that support, if provided, covers data generated in England and Wales only. Please clarify how data will be obtained from Scotland and Northern Ireland.

3. Please provide further detail as to how the patient engagement activities functioned and how the patient voice was genuinely independent.

4. Develop the patient information leaflet using appropriate lay language

5. The patient leaflet should be revised to provide details of how individuals can opt out rather than only provide a link to the website

6. Detailed description of what data is being provided to commercial providers and under what circumstances would this information be provided. It should also be confirmed whether this involves patient level or aggregated data?

7. The dataflow diagram lists patient name, however this is not listed as an identifier in the application. The applicant should clarify if patient name is to be used and if so, for what purposes

8. Detail of how and when patients be given outcomes of the study

9. Clarify that the registry is free to publish any data without commercial pressure from commercial providers

10. Clarification that this is a non-research project. The language used implies research. If this is a research project an NHS ethical opinion will need to be sought. The applicant should use the HRA decision tool to confirm.

11. The applicant should consider the provisions of the Mental Capacity Act, as support if provided, does not override any other legal provisions.

Once received the information will be reviewed at the next available CAG meeting. At this stage it may be necessary to request further information.

**b) 16/CAG/0153 – UK Renal Registry (Previously 16/CAG/0107**

Context

The original application (16/CAG/0107) was submitted and considered at the 8th September 2016 meeting, and a not approved outcome was provided in an outcome letter dated 14th October 2016. In particular, this outcome had requested that all precise data flows and items needed to be clarified in a revised submission.

That submission was also linked to a research application (16/CAG/0020) which received an initial deferred outcome requiring confirmation that support to add additional data linkages, over and above those already supported under PIAG 1-07(c)/2004 would be made in a new full submission to CAG. A revised research application (16/CAG/0064) was submitted and received a provisional approval; conditions included a revised non-research application submission.

Purpose of application

The UK Renal Registry (UKRR) collects, analyses and reports on patients with Chronic kidney disease, including those receiving renal replacement therapy, and Acute kidney injury. It receives data from renal units and laboratories in the UK.

This application is to consolidate a number of amendments, updates and extension to the original application in 2004 (PIAG 1-07(c)/2004). It seeks to adopt the same patient identifiers for all patients involved and provides updated information on dataflow and information governance.

A recommendation for class 1, 4, 5 and 6 support was requested to cover the activities outlined in the application.

Confidential patient information requested

Access was requested to forename and surname, address, postcode, date of birth, ethnicity, gender, occupation, GP registration, NHS number, Hospital name and code and hospital patient number, date and cause of death.

Support is requested to continue to link to data held by two organisations:

1. NHS Blood and Transplant,
2. Public Health England (previously known as Health Protection Agency),

New permissions are sought to link regularly to data held by two other organisations:

3. Hospital Episode Statistics (and the equivalent databases in Wales and Northern Ireland),
4. Office for National Statistics (Medical Research Information Service),

The new linkages are to enable the audit and quality assurance work of the UK Renal Registry to be extended to hospital admissions and cause of death.

**Confidentiality Advisory Group advice**

Public interest

Members agreed that there was a clear medical purpose and a strong public interest in this activity continuing.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

• Feasibility of consent

The application specified that the main reason for not seeking consent was to avoid potential reporting bias as the data is primarily collected for audit and quality assurance.

• Use of anonymised/pseudonymised data

The applicants describe the intention to move towards using pseudonymised data, however this was not possible at present.

Patient notification and objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The Registry has a patient opt out poster which provides information regarding what happens to data used and how patients can decline their data being used, a patient leaflet which details what happens to patient data, provides background to the Registry and details patient opt out.

Justification of identifiers

Members questioned the extent of identifiers, and whether these were necessary. For example, it was suggested that there should be an assessment of data flowing to and from NHS Digital, and whether there were specific flows of identifiable information that could be replaced using study ID, to reduce the flows of confidential patient information.. Members noted that, at time of next annual review, the applicants should provide evidence to demonstrate progress towards moving away from unnecessary retention of identifiers.

Patient and Public Involvement

The Registry has a patient council that meets regularly which comprises of 15 patient members and representation for all four nations. The council led on the preparation of the information provided to patients regarding the data collected by the Registry.

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State, subject to compliance with the specific and standard conditions of support as set out below. CAG expects the registry to move away from using identifiers at the earliest opportunity with evidence being provided in the annual review.

**Clarification request**

We would be grateful if you could provide clarification as to who has legal responsibility for UKRDC in terms of lines of accountability please provide this information no later than 9th January 2017.

Members sought clarification whether clinicians would only be able to access information on their own patients (in addition to seeing in reference to other aggregate data.

**Specific conditions of support**

1. Provision, at the time of next annual review, of report providing evidence of progression towards unnecessary use of identifiers, specifically in relation to data flows involving NHS Digital, and steps to investigate the provision of study ID instead of confidential patient information.

## 5. NEW APPLICATIONS – Research

### a) 16/CAG/0155 – National Neonatal Research Database (Extension)

Purpose of application

The National Neonatal Research Database contains data extracted from the real-time electronic patient records of all admissions to NHS Neonatal Units. The National Neonatal Research Database is held on a secure NHS server at Chelsea & Westminster NHS Foundation Trust. The data includes demographics, daily care processes, medications, and clinical parameters including age two-year follow-up assessments.

The National Neonatal Research Database was created to be a national resource to improve the care of newborn babies and support neonatal services through auditing, monitoring and analysing the delivery, organisation and outcomes of care, and facilitating research. It is used by a growing number and range of research groups and organisations including the Departments of Health, NHS England, and Public Health England.

The database has existing support through a historic application ECC 8-05(F)/2010; however, following the submission of an amendment in July 2016, which was not supported, CAG recommended that the particulars of this amendment should be submitted as a new application, and this was the item under consideration.

The applicants currently hold permission to receive identifiable patient data in order to link the National Neonatal Research Database to Hospital Episodes Statistics. This application seeks to

permission to extend linkage of the National Neonatal Research Database to the following additional datasets:

1. Patient Demographic Service (PDS)
2. National Pupil Database (NPD)
3. National Infant Physical Examination Programme (NIPE)
4. Clinical Practice Research Database (CPRD).

The revised application also requests to extend the personal identifiers processed to include name, to enable linkage with the NPD.

Permission was also requested to retain identifiers for a period of 20 years in order to facilitate long-term research.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover activities specified in the application.

Confidential patient information requested

Under the existing application, support was already in place for the following identifiers under reference ECC 8-05 (f)/2010 and it was agreed that these were out of scope of the CAG considerations as part of this resubmission:

- NHS Number,
- Hospital ID No,
- Date of birth,
- Date of death,
- Postcode,
- Date of admission and discharge to a neonatal unit,
- Date of event,
- Infant sex and ethnicity,
- For the Mother - NHS number and ethnicity are requested.

As part of this revised submission, the applicants requested access to the following additional item of confidential patient information:

Name – it was stated that this was required for linkage with the National Pupil Database of the Department of Education as no healthcare identifiers were available in this data source.

**Confidentiality Advisory Group Advice**

Scope of the Application

Some helpful clarification was received ahead of the meeting from Mr Eugene Statnikov around the scope of the revised application and confirmation of the amendments which the CAG was being asked to consider as part of this application. The following scope was confirmed:

- The applicants were requesting support to link identifiers held in the existing research database with the following datasets: PDS, NIPE and CRPD,
- It was confirmed that references to linkage with the National Pupil Database were included in the application in error. The applicants confirmed that this linkage was something which they intended to do in the future; however, this would form part of an amendment as it was recognised that this was likely to involve a request to release identifiers to the Department of Education, and this would involve more detailed consideration as it would relate to issues of what datasets could fall within the remit of support under Regulation 5 of the Health Service

(Control of Patient Information) Regulations 2002. It was advised that the applicants engage directly with the Confidentiality Advice Team prior to submitting any future request.

- The applicants confirmed that they were requesting to hold identifiers for 20 years, which was asserted to be in line with the NHS Record Management Code of Practice.

Public Interest

The Committee maintained that this was a very important programme which needed to be comprehensive, however, it was noted that the application did not provide any rationale to support the extended data linkages and it was unclear from the information provided how these additional linkages were in the public interest. In particular, it was noted that only minimal changes had been made to the original application form and therefore there was insufficient information provided to the members to enable them to provide a recommendation to the amendment aspects. Members agreed that further rationale was necessary to strengthen the public interest for medical purposes in the extension of linkages to each of the detailed datasets.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The CAG acknowledged that whilst the feasibility of gaining consent had originally been considered under the existing support application, it was noted that the previously cited rationale around not seeking explicit consent remained appropriate.

- Use of anonymised/pseudonymised data

This aspect had previously been considered and given support under the existing database application.

Justification and retention of identifiers

Members noted that name had been requested as an additional identifier to enable linkage with the National Pupil Database (NPD); however, it was queried whether this was still required following confirmation that linkages with the NPD were not part of the scope of this resubmission, therefore clarification was requested.

The CAG discussed the request to hold patient identifiers for 20 years and it was commented that no written justification for this requirement had been provided for consideration. Members also queried whether the extension to this retention period also applied to deceased children. Further clarification and justification around these points was requested from the applicant.

Members also considered whether there were reasonable opportunities to reduce the need to process confidential patient information in certain instances. The Committee agreed that consideration was required from the applicants around the strategies employed to assess and reduce the identifiability of the data held within the database. For example, it was noted that there could be potential for dates to be amended to age at the time of the event.

Members discussed the original outcome for the existing database application and it was noted that it was originally proposed that NHS number would be removed from the database following HES linkage, after which it was proposed that infant HES ID would be used as the key identifier. However, the CAG commented that in order to undertake the linkages with the additional proposed datasets, it

was suggested that this original outcome condition could not have been taken forward as the proposed links would not be possible if so.

Further to the CAG meeting, administrative checks were undertaken on the existing application around this point and it was confirmed that the applicants had provided progress against this condition of support at each annual review since support was recommended. It was noted from the most recent annual review report that the applicants had to date only linked 2010 data from the database with HES, the publication of which is currently under scrutiny. The applicants had stated that identifier data would be destroyed once they had received confirmation of successful linkage.

Whilst the information from the annual review provided evidence that the applicants had been progressing with the previously applied condition, it was unclear whether the amended application was requesting approval to move away from these historic conditions, in order to allow confidential patient identifiers to be retained to enable linkage with the proposed additional datasets. Clarification around this point was required in order to understand the scope of the revised application and how the request altered the existing support.

Data Flows

Members stated that the additional data flows requested by the applicants had not been sufficiently explained and it was agreed that clear information around the proposal was required, together with a revised data flow chart to account for the proposed transfer of all aspects of the requested confidential patient information; the bodies/data controllers involved in processing. Clarification was also required around how regularly data linkages with the newly proposed datasets would be carried out.

Patient Notification and objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The Committee discussed the patient notification documents which had been submitted as part of the application and it was identified that the National Neonatal Database was referenced within both the information leaflet and poster as the National Neonatal Audit Programme. Members were unclear why the project was referenced in this manner as it was potentially confusing and unclear to parents, especially as the specific application under consideration related entirely to the research database. The CAG was therefore provided with no evidence that suitable information was being made available to patients regarding this database and its purposes.

The CAG also noted that the additional data linkages and transfer of confidential patient information were not referenced in these documents and it appeared that these had not been updated. Revised patient notification materials were required from the applicants as part of the resubmission to ensure this principle was being met. Members identified that opt-out information had been included within the parent information materials; however, it was noted that this needed to be revised to extend the opt-out to future linkages with the additional datasets.

The Committee queried that whilst the withdrawal of consent or parent objection would stop the flow of data into the database, it was unclear whether this would extend to any information which had previously been transferred to the database and clarification was requested on this aspect.

Patient Engagement

The Committee noted from the application that the applicants were commencing engagement activity with parents and young adults to understand how individuals would like to be contacted in

the longer term; however, no further information had been included around this patient involvement. Members acknowledged the supportive letter received from the Bliss charity and agreed that it would be helpful to receive further information around how the applicants have engaged patients about the use of confidential patient information within the existing database, and the proposed future extension.

**Confidentiality Advisory Group Advice Conclusion**

In line with the considerations above, the CAG agreed that while supportive in principle of the amendment, further information and consideration would be required from the applicant in order for a recommendation under the Regulations to be provided.

It was agreed that existing support continues under the previously supported application reference ECC 8-05(F)/2010, for the datasets listed within that application.

**Further information Required**

In order to provide a recommendation to the decision-maker, the CAG requested that the following clarifications be responded to. Once complete responses are received, these will be considered at the next available CAG meeting, at which point a recommendation will be provided to the Health Research Authority.

The responses must be provided in the form of the following:

- A fully revised application that takes all points into account,
- A covering letter, indicating clearly what sections of the application have been amended to meet each of the clarifications listed below,
- Relevant supporting information materials.

1. Provide details of the rationale to support linkage with each of the specified datasets (PDS, NIPE and CPRD) and identify the medical purpose for each of these linkages and how each supports the public interest.

2. Confirm whether access to name as an additional identifier is still required at this time as it was noted that this had been requested in relation to linkage with the National Pupil Database, which was subsequently withdrawn from the scope of the project at the time of CAG consideration.

3. Provide a justification to support the request to retain identifiers for 20 years. This should provide relevant sections of the Records Management Code of Practice, and provide this justification in the context of why it is necessary, to support the purposes of the application, for the information to be retained for this time period. Any review periods that will be built in should also be specified.

4. In relation to the retention of identifiers, to clarify whether this 20 year time period applies to babies who have died and if so to provide a strong justification to support the requirement for this retention period.

5. Consider whether it is possible to reduce the identifiability of the information stored in the database in certain situations and provide detail around how this would be implemented if so, or strong rationale to support the decision not to do so.

6. Provide clarification around whether the revised application will request removal of this specification condition of support attached to the existing study around the destruction of NHS numbers following successful HES linkage to enable retention of this identifier in order to link with the additional datasets.

7. Provide updated specific detail on each of the data flows in relation to the proposed extended data linkages, and provide clear data flow charts to support this information.

8. Provide further information around how parent objection/withdrawal of consent will be managed in terms of data which may have previously transferred into the database prior to the objection being raised. The response should also clarify whether any data would be destroyed following an objection.

9. Provide further information around what level of patient engagement has been undertaken to date around the acceptability of holding and using confidential patient information for these purposes. Also to provide update around the work undertaken with parents and young adults around ways to maintain future long-term contact as detailed in the application.

10. Confirm how patients are currently able to understand the role of the National Neonatal Research Database, as it appeared to be currently referenced as the National Neonatal Audit Programme within the parent notification materials.

11. Submit revised parent notification materials (poster and leaflet) to address the following points:
    a. Correct inconsistencies in referencing to the database (see point six above),
    b. Include information around the data linkages with the additional proposed datasets, the transfer of confidential patient information and retention of confidential identifiers,
    c. Extend the information in relation to parent opt-out to include the linkages with the proposed additional datasets and the extended retention period.

12. Confirmation of a favourable REC opinion for the extension of the data linkage is required.

**6. MINUTES OF THE MEETING HELD ON 31 OCTOBER 2016**

The minutes of the meeting held on 31 October 2016 were received and signed as an accurate record of proceedings.

**7. CAG CHAIR REPORT**

No business was provided this month.

**8. ANY OTHER BUSINESS**

a) Members were informed that Dr Katie Harron would be taking a break in service from the Committee as she was relocating to Canada for approximately one year with. The Chair advised that Dr Harron had requested to remain a virtual Member during her during her sabbatical; however, this was not possible in line with terms and conditions. Contact would be made with Dr Harron in autumn 2017 to discuss her situation and confirm whether she will return as planned to the Committee. The Chair and members thanked Dr Harron for her contributions to the CAG during her term.

The meeting was closed.