NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

24 August 2017 at Barlow House, M1 3DZ

Group Members:

Name	*Present*	*Notes*
Ms Sophie Brannan	Yes	
Dr Tony Calland	Yes	Vice Chair
Dr Patrick Coyle	Yes	Vice Chair
Dr Lorna Fraser	Yes	
Ms Kim Kingan	Yes	
Dr Rachel Knowles	Yes	Up to Agenda Item 8 only.
Mr Andrew Melville	Yes	
Ms Clare Sanderson	Yes	
Dr Murat Soncul	Yes	

Also in attendance:

Name	*Present*	*Notes*
Miss Kathryn Murray	In Attendance	Senior Confidentiality Advisor
Miss Jennifer Blaikie	In Attendance	Observer – Leeds East REC

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies

Apologies were noted from Dr Martin Andrew.

Declarations of Interest

Application 17CAG0123 - Dr Rachel Knowles advised that the application had been submitted by colleagues within her department. Dr Knowles confirmed that she had not previously had any involvement

in the project; however, the Group agreed that this was a true conflict of interest. Dr Knowles did not participate in the application discussion, nor contribute to the recommendation issued.

Application 17CAG0126 - Dr Rachel Knowles had identified in advance of the meeting that she was the main applicant on this project and had a clear conflict of interest. Dr Knowles took leave of the CAG meeting in advance of the application review and was not present for any consideration of the proposal.

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 22 June 2017 meeting applications.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 22 June 2017 meeting applications.

3. NEW APPLICATIONS – Research

a. 17CAG0114 – Understanding Homicide against Caregivers by Individuals with a Mental Health Diagnosis

Context

Purpose of Application

This application from Mersey Care NHS Trust set out the purpose of undertaking qualitative research to gain a wider understanding of circumstances and processes under which homicide against a caregiver by an individual with a mental health diagnosis occurs. The applicants have devised a multi-level framework which will be utilised to analyse the clinical records of six patients currently detained in secure services with a conviction of murder or manslaughter against a family carer. The purpose of the study is to identify risk and protective factors in these cases to inform prevention or reduction of violence by patients with a mental health diagnosis against caregivers and to inform future research directions. The overarching aim is to inform the development of carer safety guide for use in routine clinical practice.

A recommendation for class 2, 4 and 6 support was requested to cover activity as described in the application.

Confidential Patient Information Requested

Cohort

The cohort will involve the records of six patients within the Mersey Care Trust region detained in High Secure Services with a conviction of murder or manslaughter between 2002 and 2015, of their Mother, Father, sibling or current or ex -spouse/partner, where the victim was over 16. Patients will have a range of diagnoses from psychosis, depression.

The applicants will have access to the full clinical record of the patients involved in the study; however, identifiable data will not be extracted as this is not required for analysis.

The applicants will, if possible, collate the following items to support analysis:

- Age at time of event,
- Sex,
- Ethnicity.

Confidentiality Advisory Group Advice

Public Interest

The CAG were assured that this application had a medical purpose and there was a strong public interest argument related to gaining a better understanding of any indicators which may contribute to a patient with a mental health diagnosis committing an act of violence.

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 considered the rationale which the applicants had supplied to support that consent was not feasible in this small patient cohort. It was acknowledged that the potential trauma an approach for consent about the project may cause the patient was a strong justification. It was further acknowledged that the wider public interest in the outcomes of the project strengthened the rationale for not seeking consent from patients. Members were assured that consent was not feasible for this project.

- Use of anonymised/pseudonymised data

Members acknowledged that the applicants were intending to extract pseudonymised data only from the medical records for use in analysis. The CAG was assured that, due to the complex qualitative analysis proposed, data extraction could not be undertaken by the direct care team on behalf of the applicants.

A query was raised around whether the applicants were intending to extract patient postcode from the medical record, as there was some contradiction in relation to this point across the documentation. It was agreed that clarification would be sought from the applicants around this point, as postcode was considered an item of identifiable data.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth.

The CAG acknowledged that the applicants would require access to patient identifiers in order to identify the patient cohort for inclusion in the project and to enable pseudonymised data to be extracted from the medical records.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed.

The CAG considered the inclusion criteria for the target patient cohort and the limited sample size of six patients. Members recognised the applicant's intentions to anonymise the dataset to be used for analysis.

However, it was queried whether the data extracted for analysis would ever truly be non-identifiable due to the high-profile nature of the patients involved. Whilst it had been identified that support under the Regulations was only required for the data extraction period, Members suggested that this may need to be extended for a longer duration to legitimise the retention of the analysis dataset due to the potential risk of identifiability from the anonymised data set. The applicants would need to consider this and provide confirmation of the duration of support required.

Members further commented that the GANT chart which displayed the study timeline was out of date. Confirmation of the revised timeframes for the project would be required, to clarify duration of support required.

Retention of Project Data

The Group was unclear of the proposed retention period for data generated in the study and agreed that clarification was required from the applicants. It was acknowledged that the applicants should consider the guidance provided in the above section 'Exit Strategy' around the risk of re-identification of patients from the anonymised analysis data set and required duration of support when providing response to this issue.

Data Sources – Confirmation of Data Controllership Arrangements

The CAG suggested there was potential for documentation to be stored within the medical records of the target patient cohort, which was generated outside of the health care setting including the tribunal reviews and Ministry of Justice reports. Confirmation of the data controllership arrangements for these data sources was required to provide clarity around which data sources were within the scope of the support request. It was acknowledged that the responsibility may have transferred from the external organisations to the Trust which is caring for the patient; however, the applicants would need to provide confirmation on this point.

Publication Arrangements

The CAG expressed concerns around the reporting and publication arrangements for the overall project. Whilst it was acknowledged that the research findings would be collated for publication in a generalizable fashion, Members were of the opinion there would still be risk of re-identification for such a high-profile patient group. It was agreed that a clearer explanation of the reporting arrangements for the project was required to provide assurances that the published data would not be identifiable.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The CAG acknowledged that the applicants had undertaken some service users and carer engagement around the project and the group would be consulted as the project progressed. Members requested further information around the patient group the applicants were working with, in order to gain a better understanding of their association with the research topic. It was recognised that ongoing work with a relevant patient group was important and updates would be required at annual review stage in connection with this work.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, 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 applicants had requested as part of the submission that the requirement to operate a patient notification and dissent mechanism be overridden for this proposal. The rationale provided to support this request was as a means to protect the patients to be included and prevent their wider peers being made aware of their background. The CAG was reasonably assured by the argument the applicants had presented; however, it was acknowledged that a generic poster advertising that research is undertaken on occasion could facilitate a patient notification mechanism and allow generic opt-out, but would not require specifics of the patient profile for inclusion in this study.

Members recognised that generic information may already be displayed with the secure unit as this would be good clinical practice; however, this had not been detailed within the application documentation and clarification would be sought around this point. If generic information around the potential for research within the Trust was not displayed in the relevant secure unit, the CAG agreed that this was something which would need to be taken forward. Members were prepared to waive the requirement to undertake study-specific patient notification activity due to the potential risks involved for the patient population to be included; however, it was confirmed that generic promotion of research was required to ensure this patient population could be offered the opportunity to opt-out.

Members suggested that the patients to be included within the project may have previously expressed a wider dissent around involvement in research which would need to be respected for this study.

Data Protection Act 1998 Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the Data Protection Act (DPA) 1998. Applicants must therefore demonstrate through the application that it is consistent with the DPA.

In response to queries raised around the compliance with the principles of the Data Protection Act 1998, the applicants had responded to confirm that the data processing would be undertaken by a 'not-for-profit organisation'. Whilst it was assumed this meant processing would be undertaken by NHS Staff at the Trust, clarification was required from the applicants in connection to this point, to provide assurance that no additional third parties were involved.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score for Mersey Care NHS Trust had been published in respect of version 14 (2016/17) of the toolkit; however, this self-assessment had not yet been assessed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. This would need to be addressed by the applicant.

Security Arrangements for Data Transfer

Members commented that it was the responsibility of the applicants to ensure that the proposed data transfer methods were compliant with the local NHS policy guidelines.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for Further Information

1. Confirm whether postcode will be extracted from patient records. If so, clarify whether this would be in a complete format or reduced to be less-identifiable.
2. Provide an updated GANT chart detailing the timeframe for the project.
3. Clarify the duration of support requested under the Regulations, taking account of the discussion referenced around the potential risk if re-identification of patients from the anonymised data set.
4. Confirm how long study data will be retained and in what format following the end of the project.
5. Clarification of the data sources to be included – it was acknowledged that some of the data sources referenced as forming part of the patient's health care record were generated outside of the health environment, e.g. Ministry of Justice reports, Tribunal reports. Confirmation was required around who is the current data controller for these data sources in order to determine whether these items are to be considered within the scope of the Regulations support (i.e. if the data controllership responsibility for these records has formally transferred to the Trust) or outside of the scope of the Regulations support (i.e. the external non-health organisation continues to be data controller for these records).
6. Provide a more detailed overview of the publication intentions for the research findings.
7. Confirm who the 'not-for-profit' organisation is that will be undertaking data processing, as referenced in the previously completed advice form.
8. Public and Patient Involvement – provide response in relation the following points:
   a. Provide an overview of the individuals who have been consulted around the project in the preliminary phase, to provide further understanding of their association with the research topic.
   b. Provide further information around the intentions to continue this public and patient involvement and engagement activity as the project progresses, advising how it is intended that these individuals would be approached and the role they will take in the project.
9. Patient Notifications and Dissent – provide response on the following issues:
   a. Confirm whether the Trust currently operates a generic notification system which would include the secure unit at which participants for this project would be detained, which informs patients and staff that research may be undertaken in the unit on occasion. If so – provide a copy of any information materials which are utilised to inform individuals about this.
   b. If a generic system (as described in point 'a' above) is not currently operated within the Trust and/or specifically within the patient unit, it is requested that generic information materials are developed for display within the unit. These materials should inform the patients that research may be undertaken and provide a means for objection to be raised. As detailed above – this does not need to include specifics about the project.
   c. It was acknowledged that patients may previously have registered a generic dissent against being included or approached about research – any historic objections should be respected within the project. Confirm agreement to this point and confirm how this would be managed.

10. Recommendation only – the applicants were advised to seek assurance that the proposed data transfer method was compliant with the local IG policies.

Specific Conditions of Support (Provisional)

1. Patient and Public Involvement and Engagement – provide ongoing reports, at annual review stage, of the activity which has been undertaken with the patient and public group which is associated with the project.
2. Favourable opinion from a Research Ethics Committee. **(Confirmed – 13 June 2017)**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Pending – assurance of NHS Digital review of Version 14 self-assessment remains outstanding).**

b. 17CAG0123 – Educational Outcomes after Childhood Cancer in England

Context

Purpose of Application

This application from the Institute of Child Health, University College London sets out the purpose of medical research to investigate using record-linkage, whether educational outcomes assessed through Key Stage examination results, differ in children who had a diagnosis of cancer compared to children in the general population in England. The applicants will use two national registries, the National Registry for Childhood Tumours (NRCT) which is currently held in the Cancer Epidemiology Unit at the University of Oxford and the National Pupil Database (NPD) which is held by the Department for Education to identify children with cancer as well as healthy children from a similar background to act as a control group, and retrieve their educational outcomes at Key Stages 1-5. The applicant explains that, due to the success in childhood cancer treatment, more children are surviving into adulthood than ever before (currently 4/5 children in the UK survive their cancer for at least five years).

The CAG remit extends to the patient cohort only and the disclosure of confidential patient information from the University of Oxford to the Department for Education. The processing in relation to the unaffected siblings and unrelated matched controls, does not involve patient information and as such, is outside the remit of the CAG.

A recommendation for class 4 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

The patient cohort to be studied is any child diagnosed with any form of cancer between 1991 and 2008, which is estimated to be 24,000 patients.

The following items of confidential patient identifiable information are required for the purposes specified:

- Full name – data linkage with NPD and identification of sibling controls,
- Date of birth – data linkage with NPD and identification of unrelated matched controls,
- Full address – for data linkage with NPD and identification of sibling controls,
- Previous full addresses – for data linkage with NPD and identification of sibling controls,
- Postcode – for data linkage with NPD and identification of sibling and unrelated controls and at district level for analysis,
- Gender – for data linkage with the NPD and analysis,
- Ethnicity – for data linkage and analysis.

The research team at UCL will not receive any confidential patient identifiable information; however, the following data items will be utilised for analysis:

- Deprivation scoring,
- Gender,
- Ethnicity,
- Special Educational Needs status,
- Exclusion information.

Confidentiality Advisory Group Advice

Public Interest

The Group was assured that the application defined a medical purpose into the research of educational outcomes for childhood cancer patients, which had a clear public interest.

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 Group acknowledged that the patient cohort included 24,000 historic patients and it was assured that seeking consent from this group was not practicable.

- Use of anonymised/pseudonymised data

It was recognised that the transfer of identifiable information was necessary to enable the Department for Education to link with the National Pupil Database. It was acknowledged that the project had been designed in such a fashion that research team would not have any access to patient identifiable information.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth.

Members noted the dataflow set out in the application and it was acknowledged that confidential patient information would need to be provided to the Department for Education to enable linkage with the National Pupil Database and the Group was assured that this data flow was appropriate.

The Group were unclear whether the full address would need to be transferred to the Department for Education to facilitate linkage, or whether postcode would suffice. It was agreed that clarification was required from the applicants on this point.

The CAG discussed the information which it was proposed would be returned to the research team at the University College London. It was noted that geocode was requested, which was accepted to be identifiable data item. Members noted that deprivation score was also being requested which was considered to be sufficient for the study aims and it was agreed that the applicants would be asked to remove geocode from the return dataset. Compliance with this point would be requested from the applicant.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed.

The Group was satisfied that, following clarification around the return of the geocode to the research team, the project had been designed in such a way, that the research team would not receive any identifiable data. Assurance is provided that the Department for Education would destroy the patient identifiers following data linkage. It was agreed that the arrangements appeared appropriate.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The Group acknowledged that the applicants had been working with CLICSargent, a charity which represented children with cancer and their families. It was suggested that more specific engagement could be undertaken with a relevant patient group, for example patients that survived a childhood cancer and were now adults and were likely to be part of the historic dataset for inclusion in the study. Members agreed that further work was required in this area to ensure that an appropriate patient group was involved in this project.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, 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 CAG considered the information which had been supplied in relation to patient notification and it was agreed that further work was required in this area. The study summary which the applicants advised would be displayed on various websites linked with the project did not provide an opt-out mechanism or contact details to facilitate this. Further work would need to be undertaken on the project-specific notifications to ensure it is clearly articulated how patients could raise a dissent. Members agreed that sight of revised materials was required, together with a clearer explanation of how an objection mechanism would be operated.

The applicants had referenced the information which was housed on the website for the National Registry of Childhood Tumours; however, on review Members found the data to be quite out of date and could not locate any information around how a patient could request withdrawal of their data. Members noted that, if it was the applicant's intention to rely on the objection systems operated by the NRCT, assurance would need to be provided that this mechanism was in place via their website.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted security assurance would need to be provided in relation to the Department for Education, as they would be in receipt of and undertaking processing of confidential patient information.

Data Transfer – Security Assurance

Members stated that the transfer of confidential patient information from the University of Oxford to the Department of Education must be compliant with the local IG policies.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for Further Information

1. Confirm whether full address or postcode only will be released from the NRCT database at the University of Oxford to the Department for Education for linkage.
2. Provide confirmation that the geocode would be removed from the data set to be returned to the research team at University College London.
3. Patient and Public Involvement and Engagement – provide response to the following point:
   a. Provide an overview of how patient and public involvement and engagement with the project will be improved as the project continues, providing detail of how an appropriate patient population can be engaged with around the project.
4. Patient Notification and Dissent – provide response to the following points:
   a. Patient notifications are information which will be provided to patients and members of the public, or placed in the public domain in order to raise the profile of an activity which is taking place without consent. Detail should be provided around the activity which is taking place, the patient cohort concerned, together with signposting for further information and details of how an objection can be raised. The study summary, which was submitted to fulfil the patient notification requirements, requires revision in line with this description.
   b. Further information is required to explain how a patient objection mechanism for the project will be operated together with detail around how any dissent would be respected.
   c. Provide further information around how a patient objection mechanism is operated by the NRCT.

5. Recommendation Only – the applicants should ensure that the transfer of confidential patient information from the University of Oxford to the Department for Education is compliant with local IG policies.

Specific Conditions of Support (Provisional)

1. Patient and Public Involvement and Engagement – an update report should be provided at the time of first annual review around activity which has been undertaken in relation to the revised plans submitted in response to point 3.a. above.
2. Favourable opinion from a Research Ethics Committee. **(Confirmed – Favourable Opinion issued 21 April 2017).**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Pending – Assurance for the Department for Education remains outstanding).**

c. 17CAG0135 – Population Study of Two Year Outcomes in Very Preterm Babies

Context

Purpose of application

This application from South Tees Hospitals NHS Foundation Trust set out the purpose of medical research into the two year developmental outcomes of premature babies born between 23 and 28 weeks gestation (more than 12 weeks early) during the 12 month period of 01/07/2015 to 30/06/2016. All babies born more than 12 weeks premature are offered a follow-up appointment at two years of age – the applicants intend to identify the patients and use this standard of care appointment to invite the parents to be involved in the study. The applicants also intend to collect data on infants who are lost to follow-up, deceased or whose parents do not respond and/or do not bring the child to the routine follow-up appointment.

The applicants request support to collect existing information about disability, general health, any problems with breathing, and the baby's behaviour, and also about the care the baby received whilst in hospital, and during follow up visits to hospital, using medical notes together with demographic information prior to seeking consent from the parents. The parents will then be asked to provide consent to participate. If they

refuse, they will be asked if data already gathered can be retained – this will be handled as per the parent's wishes.

A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

All babies born between 23 and 28 weeks gestation in the North East of England (Northern Neonatal Network), between 1/7/2015 and 30/6/2016. There are 114 patients within the sample.

The applicant is considered part of the direct care team at the site at which she is based; however, is not considered part of the care team for the three additional sites.

The following items of confidential patient information

- NHS number – identification,
- Date of birth – identification,
- Gender – analysis,
- Postcode – to calculate deprivation index for analysis,
- Maternal age – analysis.

Confidentiality Advisory Group advice

Public Interest

The CAG was assured that there was a medical purpose in the activity described. It was recognised that national clinical audits were already established which focussed on outcomes for babies born preterm and as such, Members were unclear what public interest existed in this proposed small-scale regional study. It had been identified within the application that there were only 114 patients on which the study would focus and the Group was not assured that any wider patient benefit could be achieved from the project outcomes, which were not already attained via the national audit programme. The Group stated that, should the applicants decide to submit a revised application, a stronger public interest argument would need to be put forward to support this project, which addressed the comments made in relation to the wider national audits.

Scope of Support Requested

The Group was unclear from the information presented exactly what the applicants were seeking support under the Regulations to cover. The documentation explained that the project was in two parts – the first focussed on the identification of the relevant patient cohort and the collation of perinatal data from the BadgerNet database and second on gathering information at or around the time of the two years follow-up.

Members commented that there was confusion within the application around which elements of the project were deemed standard care and were thus outside of the scope of section 251 of the NHS Act 2006. It was also unclear which elements of the project the applicants were seeking support to cover and whether there was any intention to link the datasets gathered within part one and two of the project.

It appeared from the documentation that the applicants were seeking support under the Regulations to enable the direct care team to pass contact information to the research team to allow further contact to be made about the follow-up appointment. Members voiced concerns around this element of the study as it remained unclear whether the research team would be chasing the parents for standard care treatment, which was outside the scope of the Regulations, or for inclusion in the research project. It was also unclear how many times the parents would be contacted by various means and Members suggested that if these

proposed additional contacts were research-related, there should be an agreed limit on the number of attempts which could be made to reach the parents. It was acknowledged that REC review of the project remained ongoing and the CAG acknowledged that this was something which would fall within the REC remit.

The CAG commented that, should the applicant decide to submit a revised application, a much clearer articulation of the project itself would be required, together with clear identification of the elements which required the establishment of a legal basis to legitimise the data processing.

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 were seeking consent from those parents who attended the two year follow-up appointment with their child. At this stage, the parent had the right to decline participation in the study and if so, the child would not continue in the project. It was acknowledged that support under the Regulations could not be used to override a formal dissent to participation and parent objections would need to be respected.

The Group considered this in line with the applicants request to collate data by other means on those patients who did not attend for follow-up and had not responded to any correspondence request. The applicants had stated that they required 100% ascertainment for the project, which was why they were seeking support to gather data for those who do not respond. Members acknowledged that as parents who attended the standard of care two year follow-up had the opportunity to decline participation in the research project; it was unlikely that the applicants would achieve a complete cohort. As such, the Group were of the view that the 100% ascertainment rationale was moot as this was unlikely to be achieved.

- Use of anonymised/pseudonymised data

The Group remained unclear why access to identifiable information was required for the project and it was suggested that, with heavier involvement from the direct care team, anonymous data could be extracted and shared with the researchers for analysis.

The NHS Act 2006, section 251 (4) outlined that provision to process confidential patient information cannot be made when a feasible alternative existed. The CAG was not assured by the rationale set out within the application, that the activity could only be achieved with support to take place under the Health Service (Control of Patient Information) Regulations 2002. Members expressed the opinion that the study outcomes could be attained either by further involvement of the direct care team or through use of anonymised data only. The CAG therefore recommended a not supported outcome to the decision-maker on basis that a practicable alternative to seeking support under the Regulations existed.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth.

Members recognised that the sample size had already been defined at 114 patients, so it was assumed that there had been previous involvement from members of the direct care team to establish the proposed numbers for the project. As such, it was unclear why the applicants required access to identifiable data in order to identify the study cohort, as this looked to have previously been undertaken. It was further commented that, due to the limited sample size over four research sites, the patient numbers were not unfeasible.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed.

Whilst Members were not entirely clear around the project design, it was recognised that for parents who attend the two year follow-up appointment, the intended exit from support under the Regulations, was through formal consent. It was unclear from the information provided whether parents would be asked to provide consent for all elements of the project, including the extraction of perinatal data, which it was suggested would already have taken place, two year follow-up information and the additional questionnaire. The applicants would need to ensure that the consenting process was complete and accounted for all elements. The Group had reviewed the information materials which were included and it was commented that the documentation did not adequately explain what would happen to patient data and further work would need to be undertaken on these materials. It was also noted that the parents' ability to opt-out of the research was not clearly articulated and would require revision within the documentation.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The Group considered the information which had been submitted around the public and patient engagement which had been undertaken and it was recognised that the focus of this work was around the consented cohort. It was not clear whether the applicants had tested the acceptability of proceeding to use confidential patient information for the project purposes, if the parent cannot be traced to provide formal consent or if the child had died in the intervening period, where it is stated that consent would not be sought and no opt-out opportunity would be provided. Members were of the opinion that, should the applicant decide to submit a revised application, further work would need to be undertaken in this area prior to submission, to show that appropriate engagement activity had been undertaken.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, 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 Group considered the information which had been provided in response to queries within this area and it appeared that the purpose of the patient notification mechanism had been misunderstood. Patient notifications, or information which would be provided to patients and the public and displayed in the public domain, in order to raise the profile of the activity which is being undertaken and provide an opportunity to opt-out of the use of data in this manner, would need to be devised for the project should the applicant decide to resubmit the application. Members suggested that particular consideration would need to be given to the cohort of deceased babies, whose parents would not be approached at all about the project, and how notification and dissent could be managed amongst this cohort.

Additional points

The CAG remained unclear about the data access and storage arrangements for the study. The application did not articulate how wider access to the BadgerNet database would be facilitated for the applicant. Members further noted that the explanation provided around the potential requirement for two project databases remained unclear. The Group agreed that additional information would be required in these areas should the applicant decide to submit a revised application.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met, and therefore advised that the application was not supported.

4. NEW APPLICATIONS – Non-Research

a. 17CAG0137 – Using HES Data to Support the Administrative Data Census

Context

Purpose of Application

This application from the Office for National Statistics sets out the purpose of using HES data to support the Administrative Data Census Project, which forms part of the wider Census Transformation Programme. The ADC (Administrative Data Census) Team is undertaking work to produce population estimates, household estimates and population and housing characteristics using administrative data, to meet demands for improved population statistics and as a possible alternative to the Census. Access to record level information will enable ONS to meet users' requirements for these, as well as satisfy commitments set out in the National Statistician's recommendation.

HES data is being requested to provide evidence of an interaction between an individual and an administrative system, this is to continue the improvement work on the administrative data population estimates. The information on whether individuals are interacting with systems can be used to develop rules to determine whether people are present in the population. The HES data is also intended to provide information around ethnicity and population characteristics.

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

Confidential Patient Information Requested

Cohort

The cohort consists of all living people between April 2010 and March 2017.

The following items of confidential patient identifiable information are required for the purposes detailed:

- NHS Number – validation and data linkage
- Date of birth – validation and data linkage
- Postcode – validation and data linkage
- Sex – validation and data linkage
- Ethnicity – analysis,
- Patient and Record Identifiers – validation and data linkage.

Confidentiality Advisory Group Advice

Public Interest

All applications must meet the minimum requirements of section 251 of the NHS Act 2006 in order for consideration to take place under the Health Service (Control of Patient Information) Regulations 2002. Review of the application raised a fundamental concern that it was not clear how this activity fell within a relevant medical purpose. Section 251 (12) of the NHS Act 2006 sets out the relevant medical purposes; the application had been submitted under 'management of health and social care services' categories.

The applicants stated that accurate and timely population estimates informed funding and resource allocation for health care services. It is stated that improved estimates on both the population size and population characteristics could provide benefits through potentially increasing the efficiency of these allocations by identifying areas with higher needs for health and social care. The applicants stated that the proposed activity could have wider patient benefit from enabling health services to be more accurately targeted to areas where particular sub-groups exist.

It reviewing this justification, whilst the CAG acknowledged the wider Government initiative that censuses conducted after 2021 would be achieved using other sources of data and the work of the Census Transformation Programme, Members were not satisfied that the use of patient data as proposed would achieve any direct medical benefit. The Group expressed the view that, having understood the aims of the project, it was unclear how an alternative argument could be supplied which could explain how this activity fell within a medical purpose.

GP Registration Data – Confirmed Legal Basis

The applicants had stated within the application that the information received from HES would be pseudonymously combined with their existing data holdings, which included GP registration data. Clarification was sought from the applicants around the legal basis under which they had received confidential patient information from the GP Registrations service. The applicants clarified that confidential patient information in relation to patient registrations was released to them by the Patient Demographics Service under Section 43 of the Statistics and Registration Service Act 2007. The Group received this clarification and it was queried whether there was scope to use the SRSA 2007 to establish a legal basis for the data which the applicants were requesting from HES. It was suggested that the applicants may wish to explore this as an alternative legal basis to seeking support under section 251 of the NHS Act 2006 and the Health Service (Control of Patient Information) Regulations 2002.

Cohort

The applicants had identified the patient cohort as all living people between April 2010 and March 2017. Some concerns were raised around this classification of the cohort as it was acknowledged that, in the first instance, the cohort description did not account for any individual who died during a hospital admission and it was unclear how this patient group would be accounted for.

The CAG considered the applicants argument for seeking HES data, which was supported by the fact the GP registration data would not be a complete and accurate picture of the true population as it was well known that certain patient cohorts did not regularly register with a GP. Members considered this and it was suggested that the only additional information which the HES data set would be able to provide was in connection to patients who presented at A&E (emergency admission or A&E appointments) who were not registered with a GP as all other activity via hospitals was undertaken on a GP referral. The Group was not assured identifying this small sub-cohort of patients provided a strong enough justification to receive the extensive data extraction which had been requested from HES. A stronger rationale to support the value of the HES extraction would need to be provided by the applicants should they consider making a resubmission.

Scope of Data Requested

The Group expressed concerns around the scope of the data requested. Whilst it had been specified by the applicants that they were not requesting any clinical data as part of the HES extraction, it was acknowledged that interaction with the HES database in itself was clinical information as this highlighted that an individual had been subject to a hospital admission.

Members also stated that, in order to support the cohort of financial years April 2010 to March 2017, the applicants had stipulated that they would require complete extraction for the full financial years of 2010 to 2017 (inclusive). It was recognised that this would involve the extraction and transfer of a considerable

amount of data which was surplus to the requirements. The rationale provided to support this additional data transfer was not sufficient and would need to be more clearly articulated should the applicants decide to resubmit.

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 was assured that, due to the number of patients to be included in the proposed activity, consent was not feasible for this project.

- Use of anonymised/pseudonymised data

The applicants state that confidential patient information would be required to enable the match keys to be added to patient-level data and facilitate linkage with the wider dataset currently held.

- Continuation of the Census

Whilst Members acknowledged that the Government initiative was for the census to be achieved by other means after 2021, it remained unclear why, when considering the proposed activity in line with Section 251 (4) of the NHS Act 2006, how the conventional census was not considered a practicable alternative to seeking support under the Regulations, acknowledging that this standard activity would be undertaken again in 2021.

Justification of identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth.

Following further scrutiny of the complete data set which was being requested from HES, the CAG noted that psychiatric information and mother's details for maternity admissions were being requested; however, no justification to support the extraction of these sensitive and identifiable details had been supplied. The Group agreed that further information would be required in this area if a revised submission was made.

Members discussed the applicant's intention to use the HES data extraction to facilitate population estimates based around ethnicity. The reliability and completeness of the recording of patient ethnicity within the HES dataset was questioned by the Group. It was unclear from the application whether the intention was to test the usability of the data within HES as it was recognised that this detail was not recorded within the GP registrations data. Further information around the purpose of requesting ethnicity data would be required in any revised application submission as the CAG was unsure of the value of this data.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed.

Members acknowledged that the applicants had described a process by which the data would be pseudonymised upon receipt into the ONS environment and it was stated that after this time, the dataset would no longer be identifiable. It was not clear what timeframe this action would be undertaken within from

the detail within the application and the CAG commented that this would need to be more clearly articulated should the applicants decide to make a resubmission.

NHS Digital – HES Data Controller

The Group was unclear from the information supplied in the application whether the applicants had previously engaged with NHS Digital, as data controller for the HES data set, around the proposed data release. It was recommended that the applicants approach NHS Digital, if they had not previously, to discuss the project.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

Members considered the information which had been supplied in relation to public and patient engagement and involvement activities and whilst it was acknowledged that ONS did have an established ongoing programme, there did not appear to be any evidence that there had been specific consultation in relation to using identifiable patient information or the purposes described within the application. The CAG suggested that, should the applicants wish to make a resubmission for consideration under the Regulations, stronger public and patient engagement activity would need to be undertaken to test the acceptability of using patient information in this manner.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, 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 Group considered the information which had been submitted to support a patient notification mechanism and some concerns were raised. It was noted that the detail did not comprehensively articulate the personal-level data which was being used in the project. The information also did not explain that ONS had an extensive existing holding, which was established under an alternative legal basis with which this data would be linked. It was commented that should a revised application be submitted, further work would need to be undertaken in relation to the patient notifications to provide clear and transparent information about the comprehensive dataset which was being created to support this project.

It was noted that the applicants were requesting a patient dissent waiver on the basis that the data would be anonymised directly upon receipt; however, the data flow processes and the timeframe for anonymising the data received was unclear in the application and the Group was not assured on this point. It was further recognised that the applicants had not referenced whether type 2 objections would be respected by NHS Digital when providing the data extract. Should a revised application be submitted to the CAG, stronger rationale would need to be supplied to support the request to waive patient objection requirement.

Additional Points

Members considered the information which included within the dataflow chart submitted to support the project. Whilst it was acknowledged that this was unclear, Members stated that, from the way the information was presented within the data flow chart, it suggested that researchers may be given access to the data to undertake analysis prior to the linkage with other data sets being undertaken. The Group remained unclear why this access would be permitted. It was noted that any recommendation of support under the Health Service (Control of Patient Information) Regulations 2002 did not permit any onward disclosure of identifiable information. It was further noted that research purposes could not be covered under any application which was submitted for consideration as a non-research project.

The Group further noted that, from the way information was presented within the data flow diagram, it appeared that the confidential patient identifiable data was being retained by DAAS at ONS under Section 33 of the DPA. It was agreed that, should the applicant decide to resubmit the application, a much clearer data flow chart would be required to address these queries.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met, and therefore advised that the application was not supported.

5. MINUTES OF THE MEETING HELD ON 22 JUNE 2017

The minutes were agreed as an accurate record of proceedings, with no amendments raised.

6. CAT OFFICE REPORT

The Confidentiality Advice Team Office Report for July 2017 was circulated ahead of the CAG meeting. The following key points were noted.

CAT Recruitment - update

Members were advised of a new appointment to the Confidentiality Advice Team who would be starting in September 2017.

CAG membership recruitment - update

Members were provided with an overview of upcoming plans in relation the recruitment of a new CAG Chair. It was also confirmed that Members recruitment would also be undertaken simultaneously.

Confidentiality Advice Management Board

Members were provided with an overview of the recent CAG Management Board meeting. It was also confirmed that

The 'Precedent Set Criteria Guidance' document was also considered and approved at the CAG Management Board. This document provides guidance for applicants around the Precedent Set review process, the agreed review criteria and standard exclusions and is designed to provide assistance around the overall review process. This document has previously been considered by members at the CAG Away Day which was held in October 2016. The document had been published on the HRA website.

Application Activity – July 2017

A separate report was provided that provided high level information on the number of applications completed within the month.

CAG Minutes – Circulation and Publication

The CAG was informed of a change to the ratification process of minutes pertaining to business which is conducted virtually in correspondence was reported to the CAG. This was an internal change in office level processes to enable timely publication of the minutes via the HRA website.

External meetings

A high-level overview was provided to Members in connection with some external meetings which Members of the CAG Chair Team and CAT had attended over the previous month.

Wider Updates

A recent number of queries have been received from applicants and system suppliers querying whether the GDPR will adversely impact on approvals provided under Regulation 5. There appears to be an expectation for the CAG to develop guidance on this area. These queries appear to arise from a misunderstanding of the GDPR implications, as those processing information under Regulation 5 of the COPI Regulations are not relying upon consent as the legal basis. The HRA Policy team is expected to issue guidance on GDPR implications relating to research in due course, separate to the role of the CAG.

7. CAG CHAIR REPORT

The Chair confirmed that there was no requirement for a report due to lack of additional business.

8. ANY OTHER BUSINESS

There were no further agenda items raised at the meeting.

Dr Rachel Knowles left the Committee meeting.

9. NEW APPLICATIONS – Research (cont.)

a. 17CAG0126 – Surveillance of Severe Microcephaly in the UK and Ireland

Context

Purpose of application

This application from University College London Great Ormond Street Institute of Child Health sets out the purpose of medical research into Microcephaly, which describes a baby with a 'small head', who has experienced poor head growth before or after birth. This rare condition may be associated with abnormal brain structure or development, and with disability, although some babies will develop normally. Many different causes of microcephaly have been described, including genetic disorders, exposure during pregnancy to environmental toxins, certain drugs, infection or malnutrition.

The study involves undertaking surveillance throughout the UK and Ireland through the British Paediatric Surveillance Unit (BPSU), a surveillance system for paediatric rare diseases. Questionnaires will be completed by clinicians (mainly paediatricians) participating in the BPSU system, who will retrieve information from routine hospital case notes. Over 13 months, we will collect reports of any newly diagnosed babies aged under one year and then collect follow-up information when these children are one and two years of age to find out about their subsequent health and development outcomes. The applicants also intend to validate the information received via the BPSU reporting with the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS), held by NHS Digital for English patients and Welsh Congenital Anomaly register (CARIS), held by Public Health Wales for Welsh patients. Linkage is also proposed with the Newborn Hearing Screening Programme (NHSP), held by Public Health England to determine whether any infants are identified through screening for a hearing impairment.

The applicants are requesting retention of patient identifiers until the children are 11 years of age to enable future linkage with educational outcome data. The request to retain the data forms part of this application; however, the future data linkage does not.

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

Confidential Patient Information Requested

Cohort

All children in England and Wales aged under three years who are diagnosed with severe microcephaly during their first year of life during the 13 month surveillance period. An approximate sample size of 400 patients is required for the analysis.

The following items of confidential patient identifiable information have been requested for the purposes defined:

- NHS number – validation and retained for future linkage,
- Date of birth – validation, analysis and retained for future linkage,
- Date of death – validation and analysis,
- Sex – validation and analysis,
- Postcode (unit level) – validation, analysis and retained for future linkage,
- Ethnicity – for analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that the application defined a clear medical purpose through research into a rare disorder, which was in the public interest.

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 Group acknowledged that the project would be undertaken using the established BPSU methodology, which was an established precedent, for which consent was determined to be infeasible.

- Use of anonymised/pseudonymised data

It was acknowledged that access to patient identifiers was required to facilitate data validation with the wider national datasets and to undertake the necessary follow-up as per the protocol.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth.

Members noted the dataflow set out in the application, the datasets and the detail provided on how the datasets would be managed and linked. It was agreed that the arrangements appeared appropriate.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed.

The applicants had requested support to retain patient identifiers until the patients had reached 11 years old to enable future linkage via the Department for Education, to assess the impact of Microcephaly on educational attainment. The Group acknowledged that whilst it was usual to request that applicants establish an exit strategy from the continued requirement to process or retain confidential patient information without consent, it was recognised that in this instance, follow-up of educational attainment at the proposed later date was essential to gaining understanding of the long-term outcomes for this patient cohort. The CAG was assured by the rationale supplied to support the retention of the data items and recommended support for this. Members asserted that the future data linkage via the Department for Education was not covered as part of this recommendation of support and it was highlighted that the applicant would need to make a further application at the time of proposed data linkage.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

Members noted that the involvement appeared to be appropriate to the activity proposed, as this included interaction with relevant charities and had tested the acceptability of using identifiable patient information without consent for the purposes set out in the application.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, 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 Group was satisfied with the patient notification and dissent mechanism which had been described which followed the standard pathway for applications utilising the BPSU methodology.

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 Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support

1. Support extends to England and Wales only.
2. Support extends to the retention of confidential patient information as described in the application until patients reach 11 years of age in order to facilitate data linkage with the Department for Education. The additional future data linkage via the Department for Education is not included within this recommendation of support.
3. Favourable opinion from a Research Ethics Committee. (**Confirmed – 31 July 2017**)
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - University College London reviewed reported grade of 66% satisfactory on version 14, 2016/17)**.

The Chair thanked Members for their attendance and contribution. The meeting was closed.