NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

12 October 2017 at Skipton House, SE1 6LH

Group Members:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Dr Kambiz Boomla	Yes	
Dr Patrick Coyle	Yes	Vice Chair
Dr Lorna Fraser	Yes	
Professor Jennifer Kurinczuk	Yes	
Dr Harvey Marcovitch	Yes	
Ms Clare Sanderson	Yes	
Dr Murat Soncul	Yes	
Mr Marc Taylor	Yes	
Dr Mark Taylor	Yes	Chair

Also in attendance:

Name	*Present*	*Notes*
Miss Kathryn Murray	In Attendance	Senior Confidentiality Advisor
Mr Sean De Riggs	In Attendance	Senior Confidentiality Advisor
Ms Natasha Dunkley	In Attendance	Head of the Confidentiality Advice Service
Mr Thomas Fairman	In Attendance	HRA Assessor – Observer
Mr Stephen Robinson (Items 5a, 5b, 5c and 5d only)	In Attendance	Corporate Secretary, HRA
Professor Charles Hay (Item 4a only)	In Attendance	17CAG0175 – Main Applicant

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Mr Stephen Robinson attended in his capacity as the decision-maker, on behalf of the Health Research Authority, for the research items considered by the CAG.

Mr Sean de Riggs was welcomed the CAG meeting. Mr de Riggs had recently joined the Confidentiality Advice Team as Senior Confidentiality Advisor. It was explained that Mr de Riggs was based within Skipton House and would be taking responsibility for the London-based CAG meetings moving forward.

Mr Thomas Fairman, HRA Assessor based within the Bristol Centre, was welcomed to the CAG meeting. It was explained that Mr Fairman was in attendance to observe the CAG in order to gain an understanding of the considerations undertaken when reviewing an application for support under the Regulations.

Apologies

No apologies were noted for the meeting.

Declarations of Interest

Dr Murat Soncul raised a potential declaration of interest in relation to item 3. It was clarified that population health was an element of his day to day role but that he had had no involvement in advising the applicant. It was agreed to note that this did not represent a conflict of interest as most roles of this type had some level of involvement in public health.

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 14 September 2017 meeting applications.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 14 September 2017 meeting applications.

3. CONSIDERATION ITEMS – NHS England Application Amendments

a. CAG 7-04 (a)/2013 Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors with existing contracts working on behalf of GPs – clarification of purpose

Background to Clarification Request

Correspondence had previously been submitted to the Advice team from a third party GP who was operating under the terms of this reference. This correspondence had raised concerns that the purpose of 'population health analytics' was inappropriately included within the scope of the approved purposes within the CAG 7-04 (a)/2013 'risk stratification' application. Assessment had taken place at the office level where

it had been initially confirmed to the applicant that this purpose did not appear to be reflected within the approved application documentation. NHS England had been invited to provide further information to support their proposal that it was included, and this information was the subject of the CAG consideration.

Applicant Clarification

The NHS England response had previously referred to a guidance document, published for the purpose of supporting data controllers once support under Regulation 5 was in place, as evidence that this purpose was included. The applicants had previously been informed that this guidance documentation did not comprise evidence to clarify or confirm the scope of an application, and any such guidance would not have been considered by the CAG as it was the applicant responsibility to ensure that guidance provided as a result of support was accurate and in line with the application detail.

The response clarified that reference to the guidance document was not intended to evidence that population health analytics was included as a purpose in the application, but to demonstrate that the term 'population health analytics' was (and is) also used to represent the processing being undertaken for risk stratification purposes.

Confidentiality Advisory Group Advice

Upon review of the originally approved application and the applicant response, members unanimously agreed that the purpose of 'population health analytics' could not reasonably be considered to be an existing and approved purpose, based upon the original application documentation. It was agreed that the overarching purpose of the 'risk stratification' application, as originally described, was understood to be limited to activity intended to target vulnerable groups.

In light of this review, members agreed to recommend to the Secretary of State for Health that processing of relevant information under this reference, for the purpose of 'population health analytics', was not currently approved as it was not included within the originally supported application

The CAG advised that should NHS England wish to expand the purposes, noting the advice from the CAG above in terms of overall scope, NHS England should consider what changes are intended to be made, and then to consider whether a new and revised application should be submitted, or potentially an amendment for a smaller scale change, as considered appropriate.

4. RESUBMITTED APPLICATIONS

a. 17/CAG/0175 Mortality Information of Patients with Bleeding Disorders (previously 17/CAG/0080)

Context

<u>Purpose of Application</u>

This application from the UK Haemophilia Centre Doctors' Organisation set out the non-research purposes of tracing mortality information for patients with bleeding disorders who are registered with the National Haemophilia Database.

This application requested support to allow data linkage via NHS Digital to receive ONS mortality information on patients who are registered with a bleeding disorder as part of the National Haemophilia Database. The required data linkage was previously approved through the Central Register under reference MR328 'Haemophilia Mortality Data'; however, a revised application has been required for the data linkage.

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

Confidential Patient Information Requested

Cohort

Patients registered within the National Haemophilia database with a known bleeding disorder. The initial application will be to cover a data gap of approximately 500 patients who are registered within the National Haemophilia Database who are known to be deceased. There will be a quarterly data linkage to capture the data into newly deceased patients within the database – it is anticipated that this will amount to around 250 patients per year.

The following items of confidential patient information will be required to facilitate the data linkage.

- National Haemophilia Database Registration Number – unique identifier to enable linkage of returned data,
- NHS number, validation/linkage
- Forename – validation – complementary to or in the absence of an NHS Number
- Surname – validation – complementary to or in the absence of an NHS Number,
- Date of birth – analysis,
- Date of death – analysis,
- Cause of death – analysis.

Confidentiality Advisory Group Advice

The Chair welcomed Professor Charles Hay, Director of the UK Haemophilia Centre Doctors' Organisation (UKHCDO): National Haemophilia Database (NHD) and main applicant for the proposal, to the meeting. Professor Hay was in attendance to provide further clarity to outstanding issues around the application.

Background

The Group acknowledged that the application was a resubmission of 17CAG0088, which was considered at the CAG meeting held on 08 June 2017. The application was initially provided with a provisionally supported recommendation. The response to the provisional outcome was considered by a Sub-Committee of the original reviewing Members. From the information provided by the applicants, a question had been raised around what legal basis was established under the common law duty of confidentiality for the retention of established National Haemophilia Database. As the legality of the existing holding remained unclear, the Sub-Committee deferred the recommendation on the application, in order to seek further clarification from the applicants.

Public Interest

The Group recognised the value of the data which was retained within the established database. Members were assured that the activity defined a medical purpose and was in the public interest.

National Haemophilia Database – Legal Basis of Existing Holding

The remit of the CAG was explained and the focus of its considerations were around what legal basis had been established under the common law duty of confidentiality to legitimise data processing. Members

acknowledged the detail which had been provided by the applicants to evidence how the activity was compliant with the Data Protection Act 1998; however, this did not address the requirements of the common law duty of confidentiality.

Professor Hay confirmed that entry into the database had been operated on an implied consent basis. It was explained that these processes had been reviewed by representatives from the Information Commissioners Office (ICO) and the local Caldicott Guardian and had been deemed appropriate. Professor Hay explained that the legal basis under the common law duty of confidentiality had never been previously been questioned. The applicant also confirmed that he was not aware of any separate legal basis, via the Department of Health or NHS England as past/current data controllers for the activity, having been established.

It was identified through discussion that the data which was collated as part of the National Haemophilia Database was used for mixed purposes – both for direct care and wider non-research purposes, which were undertaken by the applicants rather than the treating clinicians. The Group commented that the dual uses of the database may have been responsible for the conflicting guidance which had previously been provided to the applicant. It was explained that implied consent was generally accepted in relation to direct care purposes; however, this was not sufficient for secondary purposes, which required affirmative action by the individual to signal their consent to this activity. The secondary uses of the data collated, which did not relate to the direct care of the patient, required the establishment of a legal basis under the common law duty of confidentiality to legitimise the processing.

The CAG advised that should a revised submission be made for consideration, a clear articulation would be required within the documentation around which elements of the application activity the Group was being asked to consider recommending support for under the Regulations.

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 had identified from the application that the National Haemophilia Database was formed of three individual databases. These were the main database, which had been in existence since 1968, a genetic database which had been in place since 2013 and the Haemtrak database, which appeared to be more closely linked with management of the patient's condition and direct care purposes. Further information was requested around the consenting arrangements which were in place for the three elements which formed the National Haemophilia Database.

Professor Hay confirmed that the genetic database was fully consented; however, this consent related solely to the use of tissue samples and the associated genetic data. It was clarified that the consent did not extend to the wider uses of the patient's data. Professor Hay advised that the Haemtrak system was utilised to monitor the patient's condition and was more closely linked with direct care. It was explained that a two-part consent process was in place for this system which included formal consent for the wider uses of the patient's data, including the inclusion in the main National Haemophilia Database.

It was identified through discussion that two centres which provided data to the National Haemophilia Database operated a formal consent process for inclusion within the database. The applicant clarified these were the Great Ormond Street Hospital and University Hospitals Bristol NHS Foundation Trust. The applicant confirmed that other sites providing data to the database operated an opt-out basis.

The CAG further considered those sites which operated a formal consenting process. Clarification was sought around the ascertainment rate of consent which was achieved at these sites and whether there were

differences between them and other centres which provided data to the National Haemophilia Database, which made consent a more feasible option.

Professor Hay advised that he did not have any figures available around the consent ascertainment rates at the sites taking formal consent. It was further advised that, as larger centres, the two sites operating a formal consent process were more likely to be responsible for the care of patients with severe bleeding disorders who attended clinical appointments more regularly, which presented further opportunity for consent to be sought.

Professor Hay explained that of the overall database cohort, there were approximately 7,000 patients with severe bleeding disorders. He advised that, if it were deemed to be necessary, a fully consented model could be achieved for this sub-cohort of patients in approximately one year as they are required to attend clinical appointments more regularly. The applicants advised that the remainder of the patient cohort registered in the National Haemophilia Database, which encompassed approximately 23,000 patients with lesser bleeding disorders would be more problematic from which to seek consent. It was confirmed that this patient group were followed up less regularly and many patients who were registered had been lost to follow-up. Professor Hay clarified that the consenting process example which had been referenced within the previous submission related to a postal consent system, which it was known did not work and as applicants, they would not want to advocate this system. The applicant suggested that consent could be achieved from the majority of the patient cohort within a three year period.

Members recognised the difficulties which had been identified with moving towards a fully consented model; however, the applicants assertion that consent was likely to be feasible within a three year period was accepted. It was advised that should a revised submission be made by the applicants, this should include a planned overview of how a fully consented model would be adopted for the database.

- Use of anonymised/pseudonymised data

The Group was assured that the access to and processing of confidential patient information was required to facilitate the proposed data linkages via NHS Digital and other data mapping activities.

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 queried whether patient name was required for the database and what the rationale was to support this data item. Professor Hay advised that patient name facilitated data mapping between sources; however, he clarified that patients could, and some had, opted out of the use of this data item, even though they had been informed that NHS Number provided greater detail.

Members acknowledged the historic nature of the database and it was queried whether there had been improvements in the integrity of the NHS Number collation over time. Professor Hay confirmed that NHS Number had only been included within the database since 2002. He further added that prior to collation of the NHS number, the database held details on 16,000 patients, which has now increased to 30,000. The applicant advised that this was not down to an increased patient population but more accurate and complete data submission.

In relation to the proposed data linkage via NHS Digital, the applicant confirmed that the intention was to receive mortality data only. Any references to morbidity data in connection with this proposed linkage were in error.

Application Purposes

The Group acknowledged that the initial application which was made sought support under the Regulations to link with mortality information held by NHS Digital for non-research purposes; however, the revised application made reference to potential research purposes. Members queried whether research had been historically undertaken and whether this was planned for the future.

Professor Hay advised that there had been historic research undertaken on the dataset and there were plans to undertake further research in future, particularly in relation to the mortality information.

The CAG advised that there were differing submission processes in place for research and non-research activities seeking support under the Regulations. It was further identified that the appointed decision-makers also differed, with the Secretary of State for Health having responsibility for non-research activity and the Health Research Authority for research activities. Members recommended that the applicants consider the intended purposes for which data collated within the National Haemophilia Database would be used to ensure that any future submission captured all required purposes to ensure the appropriate application for support under the Regulations was made.

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 considered the additional information which had been provided by the applicant during discussion at the meeting. The Group was of the opinion that should a revised application submission be made, it would be expected that the support requested would be on a time limited basis as patient consent had been explored and provided an exit strategy.

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 received supplementary information within the revised application submission around the public and patient involvement and engagement activities which were established as part of the National Haemophilia Database's standard practices. In consideration of this information, Members commented that there did not appear to have been any specific activity undertaken in relation to the mortality data linkage activity or the retention of confidential patient information without consent. The Group recommended that additional activity was undertaken to address these two key points. If the feedback provided from the engagement activity was negative towards the activity, the CAG would take this into account when considering whether support can be recommended, or whether further actions were necessary.

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.

It was acknowledged from the supplementary information which had been provided as part of the resubmission documentation and also in discussion with the applicants that the National Haemophilia Database team operated a number of patient notification mechanisms. Members recognised that, as the initial application submission concerned linkage with mortality data for deceased patients, the applicants had not included an overview of the established communication strategy.

Members commented that the patient notification materials would require revision as part of any resubmitted application. Documentation would need to accurately describe the purposes of the application, the organisations involved together with an accurate overview of the flows of confidential patient information and clear details of how a patient could opt-out of the inclusion within the National Haemophilia Database.

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 the National Haemophilia Database had been published in respect of version 14 (2016/17) of the toolkit; however, this self-assessment had not yet been reviewed 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.

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 (Summary)

1. A revised application form should be submitted to address the following issues:
    a. Provide a clear definition of the scope of support requested under the Regulations. Consideration should be given to the inclusion of the following elements which may require support under the Regulations:
        i. The ongoing retention of the existing database,
        ii. The inclusion on newly diagnosed patients and additional data in relation to previously registered patients (for an interim period only pending the introduction of the consented model),
        iii. Data linkage with ONS mortality information at NHS Digital for patients currently registered within the database,
        iv. The purposes for which support is required acknowledging guidance provided above around the differing requirements for research and non-research activities.
    b. A clear overview should be provided around how the database activity will move to a fully consented model together with an anticipated timeframe for this process.
2. Patient and Public Involvement and Engagement – further work should be undertaken in this area to address the following points:
    a. The acceptability of processing and retaining confidential patient information without consent for the application purposes should be explored with the appropriate patient group and feedback of the outcomes provided for consideration,
    b. The proposed linkage with mortality data should also be explored to gain an understanding of patients views in this area, which should also be fed back to the CAG for consideration,
    c. It is recommended that patients and the public are engaged with around the updated patient notification materials to ensure that the revised description of the database activity is clear within the documentation,
    d. A revised plan for ongoing patient and public involvement and engagement should also be included for consideration,
    e. If the responses given by patients and the public are negative, the CAG will take this into account when considering whether support can be recommended.
3. Patient Notification Materials and Dissent Mechanisms – the patient information materials, which are utilised to inform patients of how their data is accessed and processed, would need to be revised. Updated documentation would need to be submitted for consideration by the CAG. The following points should be considered:

a. Clear information should be provided around the purposes of the application, accounting for the details provided in response to point one above,
b. An overview of the organisations involved in the application activity together with an accurate overview of the flows of confidential patient information should be provided,
c. A clear opt-out mechanism should be described, including details of how a patient would raise an objection. The applicants should consider offering levels of dissent, for example – dissent to the inclusion within the National Haemophilia Database, an overarching dissent to any secondary use of the data, or specifically for any research purposes.

4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.

5. NEW APPLICATIONS – Research

a. 17/CAG/0166 - Serosurveillance study of maternally-derived anti-GBS antibody

Context

Purpose of Application

This application from St George's University of London set out the purpose of medical research to collect comprehensive information about the amount of antibody that protects infants from Group B Streptococcus (GBS), a bacterium (germ) that can cause serious infections such as meningitis, blood poisoning and pneumonia in newborns. The study seeks to obtain antibodies from the dried blood spots taken from newborn screening cards from 150 infants with GBS that occurred during 2014. These will be compared with a matched cohort of 300 healthy controls. The applicants will identify the patient cohort from a previous surveillance activity that was undertaken with support provided by Public Health England under Regulation 3 of the Control of the Health Service (Control of Patient Information) Regulations 2002. The study will then use the antibody test developed at Public Health England to measure antibody concentrations to work out how much antibody is needed to protect babies from GBS.

The applicant proposes a case control study to compare antibody in babies with disease with those without disease for case identification, anonymisation and laboratory work. Each case will be matched with two controls for gestation, sex and ethnicity taken at the same date to make sure that the results are accurate.

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

Confidential Patient Information Requested

Cohort

- 150 infants aged 0-90 days of age born at any English hospital and identified through national surveillance database as laboratory-confirmed GBS disease between January and December 2014.

- 300 control patients matched by age, sex and ethnicity matched controls.

The following items of confidential patient information are requested for the purposes as specified below:

- NHS number – required to identify the patient,
- Date of birth – required to calculate age at diagnosis in days/weeks; enable matching by sex and gestation,
- Gender – control matching,
- Ethnicity – control matching,
- Age – analysis purposes.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that this application defined a medical purpose 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 considered the feasibility of taking prospective consent from mothers of newborn babies for the use of blood spots from the screening cards. Members recognised that the proposed retrospective methodology was more pragmatic as it enabled the applicants to identify a patient cohort from the outset. The CAG commented that the medical purpose in the activity was strengthened through the retrospective design as this would facilitate immediate outputs, whereas a prospective study could take a number of years to recruit the required patient sample. Members were assured that the proposed methodology was appropriate and prospective patient consent was not a feasible practicable alternative. The Group accepted that seeking consent from the retrospective cohort was not feasible due to the historic nature of the patient cohort and the requirement for additional disclosure to facilitate this.

- Use of anonymised/pseudonymised data

Members were assured that access to confidential patient information was required in order to trace the relevant newborn screening cards of the patient cohort and to enable the establishment of the matched control cohort.

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 Group was assured that the applicants had requested access to the minimum data items to facilitate the study linkage. Date of birth was also truncated to age within the analysis dataset.

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 was unclear around the exit strategy for the project as contradictory information had been provided around the retention of the NHS Number. The applicants had advised at one stage that the NHS Number would be deleted at sample collection; however, elsewhere it was stated that this will be retained for one year. Clarification would be required from the applicant to confirm the duration of support required under the Regulations.

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 public and patient involvement and engagement activity which had been undertaken to date was limited and no plans had been provided to undertake further activity as the study progressed. In considering what activity could be undertaken in this area, the Group identified that there was an established Group B Strep Support charity. Members agreed that the charity should be approached to facilitate interaction with an appropriate parent group. The Group recommended the charity could be invited to comment on materials to publication.

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 not specified a patient notification and dissent mechanism for the project. Members acknowledged the work that had been undertaken by the applicants to limit access to confidential patient information which would make it difficult to facilitate a meaningful opt-out mechanism without causing a delay to the project. In discussion, the Group agreed that whilst a patient notification mechanism may be successful in reaching the parents of infants who had contracted the disease, this was unlikely for the parents of the matched control cohorts. The CAG considered this together with the minimal invasion which would occur during the project and it was agreed that in these exceptional circumstances, support would be recommended without the requirement of a dissenting mechanism.

Members agreed that the applicants would be required to facilitate a patient notification system to raise the profile of the research activity which was being undertaken. It was recommended that the applicant liaise with the established Group B Strep Support Charity and explore options to utilise the organisation's website to promote the project. It was acknowledged that the notification materials should also make reference. The CAG agreed that feedback would be required at the time of first annual review around the patient notification mechanism which was established for the project.

Additional Points

The Group acknowledged that the patient cohort for the study was established from a historic surveillance study which was undertaken with Regulation 3 support. It was commented that within the application, references had been made that this historic activity had been carried out via the British Paediatric Surveillance Unit (BPSU) national surveillance system. It was clarified by the Confidentiality Advice Team that this was not the case – the project had initially been submitted as a BPSU study seeking a recommendation of support under Regulation 5 from the CAG; however, this application was not progressed beyond a provisional outcome. The applicants had sought an alternative recommendation of support under Regulation 3 via Public Health England (PHE) for this application activity. It was under this Regulation 3 support that the application activity progressed and PHE continue to retain the NHS Numbers of the patient cohort which developed Group B Strep.

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 how long the NHS Number will be retained. If it is intended to retain the NHS Number for one year, provide further rationale to justify this.

Once received, the information will be reviewed by the Confidentiality Advice Team in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm approval. **At this stage, a final approval outcome will be issued and our Register of Approved Applications updated.**

Specific Conditions of Support (Provisional)

1. Public and Patient Involvement and Engagement – further work should be undertaken in this area to address the following points:
    a. The Group B Strep Support Charity should be approached about the study to explore whether they can facilitate interaction with an appropriate patient/parent group to discuss the study,
    b. The charity should be invited to comment on patient notification materials as well as be approached around publication on their website,
    c. The charity should be invited to comment on the research findings prior to publication,
    d. An update on the above activity will be required at the time of first annual review. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
2. Patient Notifications – further work should be undertaken in this area to address the following points:
    a. Patient notification materials should be prepared to raise the profile of the study, accounting for points raised in the summary of discussion above,
    b. The Group B Strep Support Charity should be invited to display these on their website,
    c. An update on the above activity should be provided at the time of first annual review, together with copies of the notification materials that were prepared for information purposes.
3. Favourable opinion from a Research Ethics Committee. **(Confirmed – issued on 23 June 2017).** Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – Public Health England. Version 14 IGT reviewed grade confirmed as satisfactory at 72%).**

b. 17/CAG/0165 - Sensitivity and specificity of the Wessex Trauma Network Bypass Tool

Context

Purpose of Application

This application from University Hospitals Southampton set out the purpose of medical research to ascertain the sensitivity and specificity of the Wessex Trauma Unit Bypass (TUB) tool in predicting severe injuries in patients who have been subjected to trauma. The purpose of this study is to evaluate the accuracy of a tool used by ambulance staff to help them decide which hospital a patient should be taken to, having been injured in a traumatic accident. Once this has been ascertained, the data will be further analysed to understand what areas of the patient condition or type of incident are common in patients who were inaccurately identified as either having been more or less severely injured than was apparent at the scene of the incident. Once this section has been completed, the tool will be modified and tested to see if the accuracy can be improved.

The applicants will define the patient cohort for inclusion from information requested via the Trauma Audit Research Network (TARN) and the University Hospitals Southampton (UHS) Emergency Department patient record system, Symphony. Sub-groups of over and under triaged patients will be generated from the cross-reference of information. The applicants seek to access the medical records of a proportion of patients within these sub-groups to enable a wider dataset to be extracted.

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

Confidential patient information requested

Cohort

The cohort covers approximately 1000 patients (adults and children) booked in to the Southampton Emergency Department patient record system with presenting complaint 'Major Trauma' AND Level 1 trauma call placed in the Emergency Department prior to arrival of patient (based on pre-hospital pre-alert information).

The following items of confidential patient information are required for the purposes described below:

- Name – included on initial Emergency Department record,
- Date of birth – to calculate age at event which will be retained for analysis,
- Hospital number – to identify and create study identifier,
- Sex – for analysis,
- Location where the traumatic incident occurred – to see if a trauma unit was bypassed.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application activity described a medical purpose through medical research, which was within the public interest, as there was potential to improve the effectiveness of the Wessex Trauma Unit Bypass Tool to ensure accurate handling of patient care.

Requirement for Support

The Group recognised that the main applicant was part of the direct care team within Emergency Department; however, it had been identified that the applicant was not acting in her capacity as clinician within this project. Members agreed that this was an appropriate differentiation and there was the requirement for a legal basis to be established under the common law duty of confidentiality to legitimise the processing of data for the application activity.

Cohort

It had been identified within the application that the patient cohort would be collated over one year in order to minimise the impact of any seasonal variation on the data collated; however, it had not been specified what the focus year was. The detail provided within the protocol was an overview of what data would be included in the study if it was run on the latest available data from April 2015 to March 2016. Clarification would be required from the applicant around the data collection period.

Data Sources

Members acknowledged that data would be requested from the Trauma Audit Research Network database to establish the patient cohort for inclusion in the project; however, it was unclear from the detail within the application how this data would be received. The Group agreed that further information would be requested around this process.

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 was assured that, as the patient cohort was established from a retrospective sample that was potentially deceased or lost to follow-up, consent was not feasible for the project.

- Use of anonymised/pseudonymised data

Members were assured that access to confidential patient information was required to enable the wider dataset needed for analysis to be extracted from patient records. Analysis will be undertaken on a pseudonymised dataset.

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 Group was assured that the items of confidential patient information requested by the applicant to facilitate the project were appropriate and necessary. It was acknowledged that the applicants were not requesting access to any information in relation to ethnicity of the patients and Members queried whether this would be an important variable for inclusion. A recommendation would be made to the applicants around the consideration of this point.

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 have clarified that analysis will be undertaken on a pseudonymised dataset; however, a link key will be retained. Further information is required in this area from the applicants to confirm how long the link key will be retained and the duration of support required under the Regulations to legitimise this retention.

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 noted that there had been limited interaction with a single patient representative throughout the design of the project and further work would be required in this area. Members agreed that the applicants would need to provide a plan around public and patient involvement and engagement activities to be undertaken as the project progressed. The acceptability of using confidential patient information as described in the application should be tested and feedback provided to the CAG for consideration. Submission of an overview of this engagement plan would be required prior to any recommendation of support being made. Feedback around the actual activity undertaken would be required at the time of first annual review. If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

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 not described a mechanism to operate patient notifications and objections for the study. Members recognised that the applicants would be retaining patient identifiers for up to three months after

the study had ended which would enable an opt-out mechanism to be operated. It was suggested that notifications could be displayed within the hospital and via the website. The Group agreed that further clarifications would be required in this area together with submission of any patient notification materials for consideration.

Incidental Findings

Members acknowledged that there was potential for the applicant to uncover failings in patient care when accessing the patient medical records in order to extract the analysis dataset. It was unclear from the information provided within the application what mechanism was in place to manage this situation should it arise. The Group agreed that further information was required from the applicant in this area.

CAG Application Form

The Confidentiality Advice Team identified that the CAG application form which had been provided as part of the project submission had not been electronically authorised at the declarations section. Submission of an appropriately authorised application form would be required.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Evidence of the favourable ethical opinion is required before any final recommendation of support can be provided.

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 (Summary)

1. Clarify the data collection period for the study.
2. Clarify the duration for which support is requested, this is bearing in mind that it would appear that you are likely to need access to identifiable data in order carry out the case note review.
3. Provide an overview of how data would be requested from the TARN database.
4. It was queried whether the inclusion of patient ethnicity would add any value to the study analysis on the basis that the capacity to assess the extent of clinical compromise might be affected by skin colour or the ability of the patient to speak English.
5. Clarify how long the pseudonymisation key will be retained and confirm the duration of support which is required under the Regulations.
6. Clarify how any incidental findings around poor patient care which might be uncovered from patient records during the course of the in depth records review would be managed and escalated.
7. Submit an updated CAG application form to include the required electronic authorisations.
8. Patient and Public Involvement and Engagement – further work is required in this area to address the following points:
    a. Provide an overview of a patient and public involvement and engagement plan for the project, which will be implemented as the study progresses.
9. Patient Notification and Dissent – further work is required to establish a system to inform patients of the activity which is being undertaken in the project and enable patient dissent to be raised. The following points should be addressed:
    a. Provide an overview of how a patient notification and objection mechanism will be operated for the study,

b. Provide copies of any notification materials for consideration by the Group.

Once received, the information will be reviewed by a sub-committee of the original reviewing Members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm approval.

Specific Conditions of Support (Provisional)

1. Patient and Public Involvement and Engagement – a report would be required at the time of first annual review against the actual activity which had been undertaken against that which was planned (see point 7.a. above). If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
2. Favourable opinion from a Research Ethics Committee. **(Pending confirmation).**
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – University Hospitals Southampton shows a reviewed published grade at 73% satisfactory on Version 14, 2016/17).**

c. 17/CAG/0167 - ISAIAH- InveStigation of AnaemIA in Hospital

Context

Purpose of Application

This application from the University of Southampton sets out the purpose of medical research to evaluate current routine practice in the diagnosis and investigation of anaemia in secondary care.

The aim of the project is to use data from a large teaching hospital that will develop an understanding of how a laboratory diagnosis of anaemia, i.e. a haemoglobin concentration below the normal reference range set by the world health organisation (WHO), is investigated and the economic impact of these investigations.

The applicant is seeking support under the Regulations to allow the Data Analysts at University Hospital Southampton to access the electronic laboratory records to acquire the dataset for the defined study period which is all cases between 01/01/2016 – 31/12/2016, which meet the inclusion criteria. These will be matched with diagnostic codes using the digital hospital medical records. Support is also requested to enable access to a sub-cohort of approximately 10% of the patient cohort records to enable the accuracy of diagnostic coding to be checked.

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

Confidential Patient Information Requested

Cohort

All patients with a confirmed laboratory diagnosis of anaemia at University Hospitals Southampton will be included. This will encompass both male and female, aged between 16 and 110 years, who were seen between 01/01/2016 and 31/12/2016 at University Hospitals Southampton. The laboratory diagnosis is classified as a haemoglobin concentration below the normal limit set by the World Health Organisation.

Total UK sample size: 33000

The following items of confidential patient information are requested for the purposes set out below:

- Hospital Number – validation and linkage between laboratory data and patient episode information,
- Gender – for analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined a medical purpose through medical research, which was within the public interest due to the potential to provide evidence to support the standardisation of anaemia investigations. A query was raised around the scientific validity of the research proposal, should it be found the diagnostic coding included within the 10% of patient records that were checked for accuracy was found to be incorrect. Members acknowledged these potential adverse findings would be useful outputs from the study, to further evidence the issues which the applicants had identified as the rationale to support the requirement for the research proposal.

Cohort

The applicants had identified that the initial patient cohort established from the electronic laboratory records would encompass approximately 30-35,000 patients, which would be reduced to a sample of between 2-10,000 patients following the application of the project exclusion criteria. The Group was unclear how the process was being undertaken and whether confidential patient information would be physically accessed for those patients within the initial cohort. Clarification around this was point was required to understand the scope of support which is required under the Regulations.

Data Analysts – Clarification of Role

The Group understood from the detail provided within the application that a key role would be undertaken by the Data Analysts within the project; however, it was unclear who these individuals were, what their usual right of access was to confidential patient data and whether they would be accessing confidential patient information with support under the Regulations. Members agreed that further information would be required from the applicants around the role of these individuals.

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 was assured that consent was not feasible due to the size of the retrospective patient cohort to the included within the project.

- Use of anonymised/pseudonymised data

The applicants had minimised the access to required identifiers and it was noted that analysis would be undertaken on a pseudonymised dataset. The CAG was assured that the limited processing of confidential patient information which was described within the application was necessary to facilitate the data linkage.

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 acknowledged the hospital

identifier which was required to facilitate the linkage for the study was only identifiable within the specific hospital setting.

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.

It was unclear from the detail included within the application when the pseudonymisation link key would be destroyed or how long support was required under the Regulations. Members agreed that further clarification was required from the applicants in this area.

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 commented that the public and patient involvement and engagement activity that had been undertaken was limited and it did not appear that the acceptability of using confidential patient information without patient consent for the project purposes had been tested. Members noted that the applicants had proposed a patient survey; however, further detail around this was required together with an overview of the findings. If the responses given within the project were negative, the CAG would take this into account when considering whether support could be recommended, or whether further actions were necessary.

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.

Members noted that a specific patient notification and objection mechanism had not been proposed for the project. The detail provided within the application around respecting patient objection appeared to relate to standard hospital procedures, rather than specifically related to the proposed study. It was recognised that the hospital website provided clear and helpful information around the research it was involved in, though an objection mechanism did not appear to have been described. The Group agreed that the applicants would be required to develop a project specific notification mechanism, which should utilise the hospital website. An overview around how any patient dissent would be received and managed was also required prior to any recommendation of support.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Evidence of the favourable ethical opinion was required from the applicants.

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 (Summary)

1. Confirm how the initial patient cohort of 35,000 will be reduced to the focus sample of between 2-10,000 patients. Clarify who will be involved in this process and what access to confidential patient information will be required to facilitate this.
2. Further information is required around the Data Analysts who will be involved in the study to address the following points:
    a. Confirm who these individuals are,
    b. Clarify what usual right of access these individuals had to confidential patient data,
    c. Confirm whether these individuals would be processing confidential patient information with support under the Regulations.
3. Clarify at what stage of the project the pseudonymisation key will be deleted and what the duration of support required under the Regulations was.
4. Patient and Public Involvement and Engagement – further work is required in this area to address the following issues:
    a. The patient survey which is referenced within the application should be undertaken in order to test the acceptability of using confidential patient information without consent for the purposes of the study,
    b. Feedback should be provided around the activity and its findings to support the public interest in the overall activity,
    c. If the responses given are negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.
5. Patient Notification and Dissent – further work is required to establish a system to inform patients of the activity which is being undertaken in the project and enable patient dissent to be raised. The following points should be addressed:
    a. Provide an overview of how a patient notification and objection mechanism will be operated for the study,
    b. Provide copies of any notification materials for consideration by the Group.

Once received, the information will be reviewed by a sub-committee of the original reviewing Members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm approval.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee. **(Pending Confirmation).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – University Hospital Southampton Information Governance Assessment Report overall score for v14 (2016/17) – 73%, reviewed by NHS Digital as satisfactory).**

d. 17/CAG/0170 – Leicester Stroke and TIA Research Database Version 1

Context

Purpose of Application

This application from University Hospitals of Leicester NHS Trust set out the purpose of medical research through the establishment of research database focussed on stroke and TIA patients within the Trust.

The application states that there are two elements to the database:

1. Stroke Registry – includes all patients presenting to the Stroke Services with a suspected acute stroke.
2. TIA Registry – includes all patients evaluated in the TIA Clinic.

The applicant explains that both registries had been collecting data since 2008 (using different software packages) and serve as a repository for comprehensive clinical information including:

- patient identifiable information (demographics)
- clinical pathway information (e.g. source of referral, time delays)
- medical data (diagnosis, past medical history, treatment plan, result of investigations)
- outcomes (follow up data collection).

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

Confidential Patient Information Requested

Access was requested the following items of confidential patient information:

- Initials
- Full name
- Address
- NHS or CHI number
- Hospital ID number
- GP registration
- Date of birth
- Year of birth
- Date of death
- Postcode (unit level)

Confidentiality Advisory Group Advice

Public Interest

Members discussed the proposal and it was acknowledged that there were a number of queries around the purpose and methodology of the proposed database establishment, which made the medical purpose and public interest in the overall activity difficult to assess.

It was identified that there were existing national holdings of a similar nature to that which was proposed within the application. Members were unclear around what additional purpose a localised database could fulfil that could not be achieved with data requested via the established national registries.

The CAG stated that consideration clarification was required around the proposal before any determination could be made in this area.

Legal Basis of Existing Holdings

It was identified from the detail provided within the application that there were two existing holdings, the stroke registry and the TIA registry, which the applicant was intending to link to establish the proposed database. The Group was unclear what the legal basis was under the common law of confidentiality to legitimise the continued retention of this patient data. The CAG commented that it cannot currently provide a recommendation of support to disclosure from, or linkage with, a dataset where the legal basis of that dataset was unclear. Further clarification was required from the applicant to provide confirmation in this area.

Data Linkage – Proposed Methodology

The CAG recognised that there were currently two data holdings within the applying organisation; however, it was commented that the proposed methodology for linkage within this application was unclear. Members

were unclear whether the applicants were intending to merge the two databases with a recommendation of support under the Regulations or it was the intention that datasets would be linked specifically for the purposes of each individual project. It was referenced with the application that the two databases operated on different software packages, which suggested they would not be merged. In contradiction to this point, class four support was sought to cover the application activity, which covered linkage between sources.

The Group commented that there was a lack of comprehensive information in both the application form and the supporting protocol which made the proposed activity difficult to understand.

It was agreed that a clear dataflow chart to cover the proposed activity would be required to assist in understanding the flow of confidential patient information within the project. The applicants would be required to provide further clarification around the methodology proposed for the project.

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

Members acknowledged that the established registries had been in existence since 2008 and it was likely that a significant proportion of those patients who were already registered in the database could be deceased. However, the Group required further clarification around the patient numbers currently included within the registries to understand why consent would not be feasible for the retrospective element.

It was understood that these two registries were still prospectively collecting data, which raised a query around whether there was potential for any future patients to be formally approached for their consent for inclusion in the research database. This issue had not been explored with the application and the CAG agreed that further information was required from the applicant prior to any determination being made around the practicality of consent for future patients.

- Use of anonymised/pseudonymised data

It was accepted that, in order to perform the proposed linkage between the two registries, use of confidential patient information was required.

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 applicants had not provided a clear justification for the requirement of the extensive list of identifiers which had been proposed for the study. The Group agreed that, should a resubmission of the application be made, a clear articulation would need to be provided to clarify the necessity of each specified item of confidential patient information.

Members were unclear whether the applicants intended to retain confidential patient information within the proposed database. If this was the intention, the CAG commented that it was unclear why this would be necessary as it was stated within the application that no wider external linkages would be required. Further explanation was required from the applicants to clearly articulate what was proposed within the application. If it was intended that patient identifiers would be retained within the proposed research database, a stronger rationale would be required to support this.

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. There did not appear to be a defined exit strategy for the project which would move the applicants away from the requirement of support under the Regulations. Members stated that further information was required around what the applicants were actually proposing to do when establishing the research database, together with clarification around which elements of the application activity actually required the establishment of a legal basis under the common law duty of confidentiality was necessary in the first instance. Within this description, the applicants would need to specify how they intended to move away from the requirement of support under the Regulations.

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 patient and public involvement and engagement activity which was described in the application was prospective and had not yet been undertaken. It was agreed that actual constructive activity was required in this area before the CAG could consider any recommendation of support for the overall project. The acceptability of using confidential patient information without patient consent for the application purposes should be tested. A clear overview of the activity which was undertaken, together with the findings of this would need to be reported back for consideration. Members recommended that the appropriate patient groups and charities were approached to assist with this requirement. It was acknowledged that if the responses given were negative towards the proposed activity, the CAG would take this into account when considering whether support could be recommended, or whether further actions were necessary.

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.

Members noted that a specific patient notification and objection mechanism had not been proposed for the project. The Group agreed that the applicants would be required to develop a project specific notification mechanism. It was recommended that any notification materials were shared with the patient and public involvement groups to ensure they were fit for purpose and accurately explained the purposes of the research database. An overview around how any patient dissent would be received and managed was also required prior to any recommendation of support.

Research Database – Governance Protocols

The CAG recognised that the research database application requested generic approval from the Research Ethics Committee, which would enable researchers to request and utilise data from the research database without seeking their own independent ethical opinion. Further information was required around the governance protocols which would be in place to facilitate data release to researchers. Assurance was also required that any data released from the research database would conform to the Information Commissioners Office (ICO) Anonymisation Code of Practice.

Caldicott Guardian – Letter of Support

The Group commented that the mandatory letter of support from the Caldicott Guardian had not been included within the application submission. This document would be required as part of any resubmission

for the CAG consideration. Members recommended that the document specifically address the appropriateness of establishing the research database independent of the standard patient records system.

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 this section of the CAG application had not been completed. 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 assurance is required for each organisation which is processing confidential patient information under the application. This would need to be addressed by the applicant.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. The applicant would be required to provide a copy of the REC favourable decision. It was recommended that the applicant seek the ethical approval prior to making any resubmission for consideration by the CAG.

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 (Summary)

The CAG advised that due to the number of issues which had been raised around the proposal, on receiving the resubmission this would need to be considered as a new application.

1. A clear articulation of what is proposed under the application is required – the following points should be considered:
    a. Is it the intention to merge the existing datasets to create a research database,
    b. Clearly define the elements of the application activity which the CAG is being asked to consider providing a recommendation of support under the Regulations for,
    c. Confirm how and by whom any linkages between the two registries would be undertaken,
    d. Provision of a data flow chart, identifying the flow of confidential patient information and the organisations involved would be helpful,
    e. Confirm whether it is the intention to retain any confidential patient information within the database. If so – justification is required to support this,
    f. Clarify whether any wider data linkages with national datasets are proposed under the scope of support under the Regulations. If so – provide an overview of which datasets will be linked with and the justification for this.
2. Confirm what the legal basis is under the common law duty of confidentiality for the existing holdings.
3. Further information is required to clarify the medical purpose in the proposed activity and define what public interest will be achieved from the proposal.
4. Clarification around the proposed cohort size for inclusion would be required to understand the scope of support which is being requested.
5. Feasibility of consent – further information is required to address the following points:
    a. Further information is required in this area to confirm why consent is not feasible for the historical cohort.
    b. It was unclear whether prospective data would also be added to the database; however, if this was the case clarify whether consent would be taken from these patients for the use of the data for research purposes.
6. Justification is required for each item of confidential patient information which is requested for research purposes.

7. Clarification of an exit strategy from the requirement for support under the Regulations should be explored and detail provided within the application.
8. Patient and Public Involvement and Engagement – further work should be undertaken in this area to address the following issues:
    a. Actual activity should be undertaken to explore patient views on the proposed activity,
    b. This should also test the acceptability of using confidential patient information for the application purposes without consent,
    c. Feedback around the application activity would be required as part of any resubmission, detailing how and where patients/public were approached, how many people where involved and what the outcomes of the interaction were. If the responses given were negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary,
    d. An overview detailing how patient and public involvement and engagement would continue as the project progressed would also be required.
9. Patient Notification and Dissent – further work is required to establish a system to inform patients of the activity which is being undertaken in the project and enable patient dissent to be raised. The following points should be addressed:
    a. Provide an overview of how a patient notification and objection mechanism will be operated for the study,
    b. Provide copies of any notification materials for consideration by the Group.
10. Assurance would be required against the relevant NHS IG Toolkits.
11. A favourable opinion from an NHS REC is required to support the proposal. It is recommended that this is in place prior to any resubmission being made to the CAG.

Once received, the information will be reviewed at the next available CAG meeting. Deadlines for future CAG meetings are available on the HRA website and you should contact the Confidentiality Advice Team to book the application onto the next available meeting. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

6. MINUTES OF THE MEETING HELD ON 14 SEPTEMBER 2017

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

7. NHS DIGITAL ADVICE REQUEST UNDER THE CARE ACT 2014

Advice Request: Change in data controllership of births and deaths Civil Registration Data for Health & Social Care research purposes

Advice Request Summary

This advice request was considered by the CAG at its meeting on 12 October 2017.
The introductory letter provided as part of the advice request confirmed that NHS Digital is working with the Office for National Statistics (ONS) and General Registrar's Office (GRO) to confirm NHS Digital data controllership of the Civil Registrations Births and Deaths data which it holds.

This will mean that in future NHS Digital will no longer be reliant on the Statistics and Registration Service Act 2007 (SRSA) legal gateways and the other SRSA requirements for the dissemination of births and deaths civil registrations data.

The position NHS Digital has reached was submitted in a supplementary paper that set out the draft policy position. In addition, advice was sought on three specific aspects:

1. With the removal of the SRSA legal gateways and ONS Terms and Conditions should Date of Death continue to be considered as a direct identifier or as an indirect identifier?

2. Should Date of Death continue to be considered a direct identifier or as an indirect identifier in relation to data released in line with ICO Anonymisation Code of Practice?
3. Subject to the answers given to the above questions; given that there is a change in data controllership for data released for the purposes of health and social care research but no change in the civil registration data set is there any impact upon existing 'Section 251' approvals?

Confidentiality Advisory Group Advice to NHS Digital

Members welcomed the attendance via teleconference of Professor Martin Severs and Ms Joanna Treddenick from NHS Digital, and found their presence helpful in providing necessary context and background to the submitted information. The following presents a high-level summary of the CAG discussions.

- It was explained that the overarching purpose was part of a broader piece of work to seek to improve data sharing and unnecessary burdens upon researcher access, and was linked to a broader programme of work led by the Research Advisory Group.

- Members questioned why the focus was on mortality data, although birth data was technically included, and it was explained that access to mortality information was a key issue for researchers; and while often this could be pseudonymised often researchers required access to full date of death in order to establish 30 and 60 day mortality.

- It was confirmed that Directions were already in place to effect this change, however, a transition date had yet to be agreed, although an indication was that this was hoped to be the beginning of November 2017.

- Members expressed their understanding that Parliament, when debating the Statistics and Registration Services Act, had felt that date of death warranted specific mention as an identifier, in addition to the report 'Information: To Share or Not to Share? The Information Governance Review' ('Caldicott 2').

- Members expressed some nervousness as to whether the change would involve a change in scrutiny that would follow as a consequence. It was noted that, with the proposed change in data controllership, if date of death is considered to always render a dataset identifiable, then disclosure under Regulation 5 of the COPI Regulations would include consideration by CAG. It was noted that if classified as an indirect identifier, that this could be perceived as a mechanism to avoid this independent level of scrutiny. NHS Digital explained that previous consultation had been undertaken with ONS and they had confirmed that date of death was assessed in terms of risk only when combined with additional datasets. NHS Digital confirmed that any such requests would in future be reviewed via the NHS Digital IGARD processes.

- Members questioned whether the proposed change would have an impact on the management of 'Type 2' objections. It was confirmed this will have an impact as if relevant information is not considered identifiable then 'Type 2' objections would not need to be applied.

- It was confirmed that due to the standard conditions applied to supported applications under Regulation 5 of the COPI Regulations 2002 that this condition of support would continue to be upheld by NHS Digital in relation to 'section 251' applications advised against by the CAG.

- Members questioned what the intentions were for a public explanation of the proposed changes. It was highlighted that in terms of maintaining public confidence in the appropriate handling and dissemination of information that there could be a risk this could be perceived as a loss of public control, and therefore it would be incumbent for NHS Digital to ensure that there are appropriate, proportionate and effective controls in place to mitigate against risks.

- Members also highlighted whether any discussions had been undertaken with the National Data Guardian. NHS Digital advised that it would be helpful to receive the CAG advice so they could report to the Research Advisory Group, and that they could return to the CAG after they had sought advice from the National Data Guardian.

CAG Advice Conclusions

1. Members noted that considering the proposed transition date of early November 2017, the advice request appeared to have been submitted close to this date, and it would have been preferable if it had been submitted at a much earlier stage as members were aware that activity around this aspect had been progressing as part of the Research Advisory Group since March 2017. CAG noted that in order to ensure that its advice was robust and considered, sufficient time was required to consider and formulate its advice and this should be taken into account when submitting future advice requests. As such, where action prior to implementation is recommended, earlier engagement with the CAG would be recommended in future to help mitigate against any negative impact on implementation timescales. It was also noted that it would not be appropriate for the CAG to provide a few lines to summarise its advice as requested, and that a considered response would be provided no later than 5 days following the meeting.

2. CAG advised that work should be undertaken by NHS Digital to avoid potential negative public perceptions that the change could involve a perceived reduction of the current scrutiny involved regarding the disclosure of confidential patient information. CAG advised that:

3. This could potentially be achieved through ensuring there are equivalent and proportionate robust controls under the proposed new approach, as is in place for the existing approaches and processes.

4. There should be authentic public messages developed to explain how the controls are proportionate and appropriate and that there is no greater risk to patient confidentiality under the proposed new approach. Also, how the proposed approach is consistent with the assessment of identifiability within the system as a whole.

5. Any disclosures should be consistent with the Information Commissioner's Office Anonymisation Code of Practice.

6. CAG advised that NHS Digital should engage with the National Data Guardian, and should only proceed if she is content with the anticipated changes and transition arrangements, including the level of NHS Digital scrutiny. It was advised the consultation with the National Data Guardian should include the following:

   a. The move to treating date of death from a direct to an indirect identifier as this was originally described as a direct identifier in 'Caldicott 2'.

   b. Whether the National Data Guardian is satisfied with the proposed public explanation of any change.

   c. Whether the shift remains effective and proportionate in terms of the risk factors involved, and any subsequent messages.

8. EDUCATION ITEM SUGGESTIONS

The Group discussed potential future education items. It was suggested that a follow-up item around the General Data Protection Regulation (GDPR) should be arrange to compliment the session which was delivered as part of the CAG away day. It was advised that the HRA would be issuing guidance around the GDPR, which be shared with CAG Members for information once available. It was

acknowledged that a further session could be arranged once further information is available around the implementation of the GDPR.

9. CAG CHAIR REPORT

The Chair's Report for August 2017 was circulated for Member information.

10. ANY OTHER BUSINESS

No other business was raised.

The Chair thanked Members for their time and consideration and the meeting was concluded.