Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

04 October 2018 at Director's Boardroom, IWM London, Lambeth Road, London, SE1 6HZ

Present:

Name	*Present*	*Notes*
Professor William Bernal	Yes	
Dr Malcolm Booth	Yes	
Dr Tony Calland MBE	Yes	Chair
Dr Lorna Fraser	Yes	
Mr. Myer Glickman	Yes	
Mr Anthony Kane	Yes	Lay Member
Dr. Simon Kolstoe	Yes	
Dr Harvey Marcovitch	Yes	
Mr Andrew Melville	Yes	Lay Member
Dr Murat Soncul	Yes	Not in attendance for Item 3.a.
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Ms Amanda Hunn	HRA Joint Head of Policy
Miss Kathryn Murray	Senior Confidentiality Advisor

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

There were no apologies received for the meeting.

The Chair welcomed Ms Amanda Hun, Joint Head of Policy at the HRA to the meeting, who was attending in her capacity as nominated decision-maker for the Health Research Authority.

The following interests were declared:

Agenda Item 4.b. Application Reference 18/CAG/0159

- Dr Lorna Fraser, CAG Member, advised of a conflict with the application in advance of the meeting. The CAG agreed that whilst Dr Fraser could remain in the room during discussion, she would not be involved in the consideration or recommendation for the item.

- Mr Myer Glickman, CAG Member, raised a conflict with the application at the meeting. The CAG agreed that whilst Mr Glickman could remain in the room during discussion, he would not be involved in the consideration or recommendation for the item.

2. APPROVAL DECISIONS

The following decisions were taken in relations to the relevant CAG recommendations.

Secretary of State for Health and Social Care Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health and Social Care (SofS) agreed with the advice provided by the CAG in relation to the **06 September 2018.**

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the **06 September 2018** meeting applications which had been shared for approval. The advice in relation to two of the applications which had been considered at this meeting remained pending and would be provided for approval in due course.

3. RESUBMITTED APPLICATIONS (Non-Research)

a. 18/CAG/0166 - National Clinical Audit for Specialist Rehabilitation following major Injury (NCASRI) – Transfer of Controllership Arrangements

Context

Purpose of application

This application has been submitted by the Trauma Audit and Research Network (TARN) for non-research purposes. The application seeks support under the Regulations for the change of controller of the confidential patient information which was collated under the National Clinical Audit of Specialist Rehabilitation following Major Injury (NCASRI) its physical transfer to TARN.

The National Clinical Audit of Specialist Rehabilitation following Major Injury (NCASRI) was commissioned by the Healthcare Quality Improvement Programme (HQIP) on behalf of NHS England to examine current provision of services for patients who have suffered severe injuries. The UK Specialist Rehabilitation Outcomes Colloborative (UKROC) submitted the application on behalf of HQIP. The NCASRI audit application was initially considered by the CAG in September 2016 under application reference 16/CAG/0108. The audit received a final recommendation in January 2017. The audit was completed on 30 June 2018 when its three year National Clinical Audit and Patient Outcomes Programme (NCAPOP) contract ended.

The Trauma Audit and Research Network (TARN) is the national clinical audit of trauma care. It is not part of the NCAPOP suite of audits commissioned by HQIP on behalf of NHS England. TARN currently operates with support under the Regulations via application ECC 7-05(g)/2011.

UKROC is a national clinical database which routinely collects key information about every patient admitted to a specialist rehabilitation unit in England. It is not commissioned by HQIP and processes confidential patient information under direction from NHS England.

A key component to the National Clinical Audit of Specialist Rehabilitation following Major Injury (NCASRI) was to undertake record level linkages from the TARN and UKROC datasets in order to be able to track individual patients discharged from major trauma centres to identify those that subsequently received specialist rehabilitation.

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

Confidential patient information requested

Cohort

All patients who were included in the National Clinical Audit of Specialist Rehabilitation following Major Injury, which operated from 01 July 2016 to 30 June 2018.

The following items of confidential patient information would be transferred within the National Clinical Audit of Specialist Rehabilitation following Major Injury (NCASRI) dataset from UK Specialist Rehabilitation Outcomes Colloborative (UKROC) to Trauma Audit and Research Network (TARN). Information will be retained in an identifiable format to facilitate future linkage:

- NHS number,
- Date of birth,
- Postcode (District Level),
- Date of treatment,
- Date of death.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, through the management of health and social care services. Members were assured that as the audit dataset was a valuable resource, it was not within the public interest to request deletion of this. However, the purpose of the ongoing retention and how the data would be used in the future was unclear from the application.

The Group acknowledged that there was a time pressure around establishing an alternative legal basis for the retention of the audit data following the contract termination in June 2018. HQIP had confirmed in correspondence that the transfer should be completed by 30 November 2018. Members were content to provide a recommendation of support to the change of controller for the data set and its transfer to TARN; however, it was agreed that this would be for an interim period of six months only. An assessment should be undertaken within this time period of the planned future use of the audit data. The outcome of this assessment should be fed back to the CAG in order to establish public interest in the ongoing retention of the dataset. This report would need to be supported by an amendment to extend the duration of support, if this was determined necessary.

Scope of Support

It was noted where support is provided, it is given to the people, purposes, data flows and items. The Secretary of State for Health and Care approves non-research applications and cannot approve

applications that have a research purpose. This project had been submitted as a non-research application and any recommendation of support which was approved would be for non-research purposes only.

Cohort

Confirmation of the number of patients included within the audit dataset was requested for information purposes.

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 recognised that seeking consent from patients included in an audit dataset which had been established with support under the Regulations was not a feasible task. No issues were raised in this area.

- Use of anonymised/pseudonymised data

The applicant explained that a potential future activity may involve linking the audit dataset with wider administrative information held by NHS Digital. This could not be achieved if confidential patient information was removed from the audit dataset. No issues were raised in this area.

Justification of identifiers

The Group recognised that the items of confidential patient information requested were those already retained in the audit dataset. These data items were not excessive and appeared proportionate to facilitate future linkage. No issues were raised in this area.

Exit Strategy

The applicant had stated that an annual assessment would be carried out around on the ongoing requirement for retention of the audit dataset. The CAG agreed that further information was required to understand what this assessment would entail.

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. It did not appear that specific activity had been undertaken to test the acceptability of the ongoing retention of the audit dataset; however, Members recognised that the TARN network had an ongoing programme of activity in wider areas. No concerns were raised in this area.

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 to objection and mechanism to respect that 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 2018. The Group agreed that a specific communications strategy would need to be put in place to inform patients and the public of the ongoing retention of the audit database and the transfer of controllership arrangements. This should also provide a mechanism for patients to raise an objection to the ongoing retention of data. The applicant would be asked to provide copies of any documentation, together with an overview of where this would be made available and details of how any objections would be respected.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation (GDPR) and Data Protection Act (DPA) 2018. The information provided at section (r) of the application form was received; however, the Data Protection Act 1998 had now been superseded by the GDPR and DPA 2018. The applicant would be asked for further information to show how the proposed activity was compliant with Article 5(1) – principles (a)-(f) of the GDPR.

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 Secretary of State for Health and Social Care, 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 the number of patients included within the NCASRI dataset.
2. Clarify how the requirement for ongoing retention of the data would be assessed on an annual basis.
3. Patient notification and dissenting documentation should be drafted which describes the ongoing retention of the NCASRI audit dataset and provides a mechanism for dissent to be raised. An overview of where information will be displayed is required together with details of how any dissent would be respected.
4. Provide further information to show how the proposed activity is compliant with Article 5(1) – principles (a)-(f) of the GDPR.

Specific conditions of support (Provisional)

1. Support is extended for a six month period only from the date of the final recommendation. Within this time, an assessment should be undertaken to establish the future purposes of the only going data retention. A report should be provided to the CAG in order to establish an ongoing public interest in the retention of the dataset. This would need to be supported by a duration extension amendment as appropriate.
2. Support extends to non-research purposes only.
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Trauma Audit and Research Network, published satisfactory reviewed grade on V14.1, 2017/18**).

4. NEW APPLICATIONS – Research

a. 18/CAG/0158 – The Northern Region Young Persons' Malignant Disease Registry

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research through the continued building of the Northern Region Young Persons' Malignant Disease Registry. This Registry was first established in 1968 and is used to underpin a programme of epidemiological and applied health research investigating incidence, survival and aetiology of cancer occurring in children and young people. The registry aims for complete coverage and includes all individuals aged 25 or under who have been diagnosed with a malignant (or benign central nervous system) cancer whilst resident in the area formerly known as the Northern Health Region. This is the geographical area covered in 2006 by the North East Government office of England and North Cumbria (the area covered by the North East Strategic Health Authority in 2006).

A recommendation for class 1, 2, 4, 5 and 6 support was requested.

Confidential patient information requested

All patients aged 25 and under who reside within the historic North East Government Office of England and North Cumbria area who are diagnosed with a malignant (or benign central nervous system). Patients living elsewhere in England are also eligible for inclusion if their cancer treatment has taken place in any of the hospitals operating within the Northern Health Region. The registry includes information on this patient cohort dating back to its establishment in 1968. Approximately 150 patients were added to the registry each year.

Data is provided from GP practices, Hospitals and wider NHS Sources. The following items of confidential patient information are recorded within the registry for the purposes identified:

- Database Registration number – unique identifier
- NHS Number – sample validation and linkage,
- Name – sample validation,
- Date of birth – sample validation, linkage and analysis,
- Sex – sample validation and analysis,
- Gender – analysis,
- Ethnicity – sample validation and analysis,
- Full Address and postcode (at diagnosis) – sample validation and analysis,
- Full Address and postcode (at birth) – sample validation and analysis,
- Full Address and postcode (current address) – sample validation and analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members recognised the value of the registry and were assured that there was public interest in the activity both historically and moving forwards, which was evidenced by the research outputs from use of registry data.

Northern Region Young Persons' Malignant Disease Registry – Legal basis of historical processing and existing holding

This specialist registry had historically operated under the overarching support provided to the UK Association of Cancer Registries (UKACR) via Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002. Following organisational structure changes from April 2013, a number of the regional cancer registries were novated over to Public Health England (PHE) under application reference PIAG 03(a)/2001. The Northern Region Young Persons' Malignant Disease Registry was not included within the local registries which novated to PHE at this time. It is understood that PHE undertook correspondence with wider registries which did not novate across to explain that an individual application should be made to provide a clearer legal basis.

It was unclear under what legal basis, in relation to the common law duty of confidentiality, the registry had operated since this time. In response to queries, a representative for the applicant explained that submission of this application to the CAG had been delayed due to the requirement to establish an NHS IG Toolkit in order to meet the mandatory conditions of support under the Regulations. It was further explained that retrospectively the registry was relying on overarching public interest as the legal basis in relation to the common law duty of confidentiality to legitimise the processing of data.

It was confirmed that the registry had continued to collect information in relation to newly diagnosed patients, patients currently in the care of a hospital within the registry catchment area and to enable

continued follow-up with patients who had been discharged from hospital care. Cross-checking with wider registries and NHS administrative datasets held by NHS Digital, Public Health England and wider NHS Trusts had ceased in the intervening period due the requirement to establish data-sharing agreements.

The CAG acknowledged that prior to April 2013 the registry had historically operated with a clear legal basis. Good practice had been maintained in the intervening period from April 2013, although the legal basis supporting the registry operation was unclear. Members agreed that this was a valuable resource and appropriate steps were now being taken to ensure that the registry was operating to current legal frameworks with a clear legal basis, under the common law duty of confidentiality, moving forwards.

Scope of the Application

The purpose of the application was to seek a recommendation of support under the Regulations to legitimise the ongoing retention of information currently held within the registry and the prospective disclosure of information from NHS Trusts and GPs within the registry in relation to newly diagnosed patients and follow-up of those already within the care to the registry.

The CAG stated that a recommendation of support under the Regulations could not be retrospectively applied to legitimise the processing and retention of data which had previously occurred without an established legal basis. However, Members agreed that a recommendation of support could be given to the future retention of the established dataset and prospective disclosure of confidential patient information into the registry. The Group recognised that there were outstanding issues which needed either clarification or further action from the applicant before a final recommendation of support would come into effect. On this basis, it was agreed that the applicants would be advised to temporarily cease all data collection and processing, until support under the Regulations could be recommended to legitimise the registry practices.

The application described prospective linkages with NHS Digital and Public Health England, which it was stated would form the basis of a future amendment. The CAG stated that as the purpose of this application was legitimise the registry practices, these prospective linkages with wider NHS organisations would not be supported at this time. It was agreed that the application form should be revised in order to clearly set out the scope of the initial application. This would ensure that there was a clear audit trail evidencing the scope of the initial application. Subsequent amendment submissions would evidence an audit trail in terms of any requested wider data linkages.

Regulation 2 or Regulation 5 Support

It was recognised that the registry had historically operated with support under Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002; however, the current application had been submitted for support under Regulation 5. It had been identified within the application that future data sharing with the National Cancer Registration Service at Public Health England was proposed. The Group agreed that the applicant should explore with PHE, as part of the conversation around the data sharing agreement, whether there was scope for the registry to be adopted under the existing Regulation 2 support. Feedback would be required at the time of first annual review around the outcome of these discussions.

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 recognised the value of the registry was increased through complete case ascertainment and there were issues around operating a consented model for the registry due to the potential for patients to be deceased. There was an established precedent for both the National Cancer Registration Service

(NCRAS) operated by PHE and wider local cancer registries to operate without consent. Members were content to provide a recommendation of support in line with this established precedent.

- Use of anonymised/pseudonymised data

The applicant stated that anonymised data was not of a sufficient resolution to enable meaningful analysis to be carried out. It was further recognised that linkage with wider datasets and follow-up of patients within the registry would not be possible without access to confidential patient information. The Group raised no concerns in this area.

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. Discrepancies had been identified between the application form and supporting documentation around the definitive list of confidential patient information required for the registry aims. Clarification was provided that the confidential patient information detailed in the supporting protocol document was the accurate list.

Members were assured that the items of confidential patient information which had been specified within the protocol were appropriate and proportionate to achieve the registry aims. As longitudinal follow-up of patients would be undertaken, it was acknowledged that there was a requirement for ongoing retention of confidential patient information for living patients. It was noted; however, that date of death had not been cited as a required identifier within the protocol. This would be queried with the applicant.

Data Flows and Onward Access

The CAG noted that patient follow-up via GPs was currently operated on a hard copy, postal-based system. It was commented that this was a less then desirable system in terms of information security. The applicants would be asked to explore the viability of moving this to an electronic-based system to facilitate a higher standard of security assurance. Feedback would be required around this element prior to any recommendation of support coming into effect. A strong rationale would need to be provided, should it be determined that an electronic system could not be established.

From the information provided at Q21, it was suggested that data released from the registry to third parties would be done so in an identifiable format. Members were very clear on their understanding that support under the Regulations does not permit onward access to identifiable data without consent. Researchers who required access to confidential patient information would be required to establish a legal basis in relation to the common law duty of confidentiality to support this disclosure.

At the same question within the application form, it was stated that once data was released from the registry, Newcastle University was no longer responsible for its safekeeping. In response to queries, it was clarified that any data release would be subject to a signed data sharing agreement. The Group stressed that, as controller for the registry, Newcastle University was responsible for establishing appropriate safeguards for data which was released from the registry.

Registry Data Storage

From the detail included within the application, it appeared that the registry database stored all confidential patient information together with the wider clinical information which would be utilised for analysis. Members commented that it was standard practice to separate identifiable information from clinical information, facilitating linkage via unique study ID. It was agreed that clarification would be sought from the applicant around the current storage practice. If all information was currently held in the same database, the applicants would be asked to take steps to separate confidential patient information from clinical information and explain how and when this would be achieved.

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 registry continued to hold confidential patient information in relation to all registered patients since its inception on 1968. It was commented that a significant proportion of these patients were likely to be deceased due to the historical nature of the cohort and the poor prognosis for cancer patients. The CAG was unclear why the registry continued to hold confidential patient information in relation to this sub-cohort of deceased patients. The applicant would be asked to provide a strong justification to support this retention or be required to reduce the identifiability of the dataset held in relation to deceased patients. Clarification was required around how this would be managed, what the resulting dataset would contain and confirm an agreed protocol to manage this prospectively.

It was stated that should the registry be closed for any reason in the future, such as lack of funding, it was envisaged that confidential patient information would be retained for a further 10 year duration. The CAG reminded the applicant that should a significant change of circumstance occur in the future, relevant notifications would need to be made with supporting amendments where relevant, to ensure there was an appropriate legal basis was in place to support the proposed retention period.

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. Information has been provided around how the registry was promoted in the public arena, describing linkages with wider patient and public networks. Members were however unclear whether the activity cited specifically related to the registry. It was also unclear whether the applicant's had tested the acceptability of the registry's use of confidential patient information without consent.

The CAG agreed that further activity was required in this area which focussed on seeking views about the registry, how it operated, including the ongoing retention and processing of confidential patient information in order to test the acceptability of this with a relevant group. This was of particular importance as the registry had been operating for some time without a clear legal basis. The Group noted reference to a children and young people's group within the application which may present a valuable opportunity to seek the views of relevant patient-base. It was further commented that the applicant's would need to think about the patient cohort included within the registry, which include information on patients who were now adults that had suffered a childhood cancer and explore ways of engaging with this patient cohort. Feedback is required from the activity which is undertaken, explaining who was approached, what format the activity was in, together with an overview of the findings. 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 to objection and mechanism to respect that 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 2018. The registry would be promoted via information leaflets, which had been provided for both parents and children, which will be provided by treating clinicians and also be made available the appropriate clinical treatment areas. A website had also been designed which would go live once the appropriate regulatory approvals were in place for the registry. It was further explained that the registry would be promoted at various local events, including the children's cancer run. Members were assured by the communications strategy which had been established to promote the registry within the public arena. It was commented that the documentation provided included references to the Data Protection Act 1998, which had been superseded. All documentation would require review and revision to ensure that this referenced current data protection legislation.

The CAG commented that the information provided about the objection mechanism was unclear and further clarification was required around how this would implemented in the local registry and how this would link with any objections which had been notified to the National Cancer Registration Service (NCRAS) operated by PHE. Members agreed that a clear overview was required around how the registry would operate a dissenting mechanism locally, clarify how any objections notified locally would be reported to the national registration service and confirm how any objections notified at a national level would be implemented to the local registry.

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. A copy of the favourable ethical opinion is required prior to any final recommendation of support coming into effect.

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. All data collection and processing should be ceased temporarily until such time as a final recommendation of support can be issued under this application reference.
2. Support is not currently recommended for linkages and cross-checking with wider NHS administrative datasets held by NHS Digital and Public Health England. An amendment to the application should be submitted at the time when support is in place to legitimise the current practice of the registry.
3. A revised application form should be provided which removes references to future linkages (as described at point two above), to ensure that an accurate audit trail is in place the current activity for which support is requested.
4. Confirm whether date of death is recorded within the registry.
5. Explore the potential of establishing an electronic data sharing process with GPs. If this is deemed possible, an overview of the process should be provided for information purposes. If this is not deemed feasible, a strong rationale would be required to support this rationale.
6. It is reminded that support under the Regulations does not permit the onward disclosure of confidential patient information to third parties. An alternative legal basis would need to be established in each case to support onward disclosures.
7. Provide assurance that appropriate safeguards would be built into any data-sharing agreements with applicants wishing to use registry data.
8. Confirm whether confidential patient information and clinical information is stored together within the registry. If so, steps should be taken to separate the information, linking by study ID to strengthen security.
9. Justify why confidential patient information continues to be retained in relation to the deceased patients. If there is no ongoing requirement to retain this information, confirmation should be provided around steps which would be taken to reduce the identifiability of information held on deceased patients, what data would be retained, the timeframe for implementing this process and protocol for prospectively managing this moving forward.
10. Further activity is required to seek the views of a relevant patient and public group about the registry, how it is operated and to test the acceptability of the use and ongoing retention of confidential patient information in order to achieve the registry's purposes. Feedback is required around the activity which has been undertaken, the demographics of the individuals approached and the format in which this was carried out, together with an overview of the findings. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, or whether further actions are necessary.

11. Patient information materials should be reviewed and updated in line with current data protection standards.
12. Clarify how the objection mechanism would be operated for the registry – this should explain how a patient can raise an objection to the use of their data within the local registry and confirmation of how this would be respected and any interaction with the National Cancer Registration Service (NCRAS) operated by Public Health England.

Specific conditions of support (Provisional)

1. Explore the potential for the registry to be adopted under Regulation 2 support with Public Health England. Feedback from the outcomes of this discussion should be provided at the time of first annual review.
2. Favourable opinion from a Research Ethics Committee (**Pending**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Newcastle University, Health and Social Care Data, published satisfactory reviewed grade on V14.1, 2017/18**).

b. 18/CAG/0159 – Environment and family risk factors for children's hospital admissions

Context

Purpose of application

This application from University College London set out the purpose of medical research which aims to investigate the impact of environment and socio-economic factors on hospital admissions in children. The project will use an established birth cohort of infants born in England between 2005 and 2014. This will be linked by the Office of National Statistics (ONS) to 2011 Census Data and small area level data on air pollution and building characteristics in order to create a dataset to facilitate analysis.

The birth cohort was established with support under the Regulations via application PIAG 2-10(g)/2005, which was subsequently amended under application reference CAG 9-08(b)/2014. The amended application linked the birth cohort data with HES data at NHS Digital to collate information on mothers and babies admitted/readmitted to hospitals in the first year of birth. An amendment was subsequently supported in May 2016 which linked the dataset with ONS mortality data to collate additional information around deaths in infants aged over one year and maternal deaths within one year of delivery of the child. City, University of London is the controller for the birth cohort information which is retained by ONS.

The application has been submitted for consideration by the CAG to seek support to use the data held within the established dataset for the wider research purposes described within the application. Support is also sought for the processing of confidential patient information which will be undertaken by ONS to link this dataset with Census, air pollution and building characteristic information. These supplementary datasets do not fall within the legal definition of confidential patient information, as set out at section 251(11) of the NS Act 2006, and processing of this information would not fall within the remit of the CAG to support. The dataset with which the birth cohort will be linked are as follows:

- 2011 Census information (for births between March 2010 and March 2012 – one year before/after Census) – data collected will include information on overcrowding, house type and tenure, type of heating, mother and fathers length of stay in the UK and knowledge of English,
- Department for Environment, Food and Rural Affairs information on full postcode level data on annual levels of eight specified pollutants modelled using atmospheric transport models,
- Information around distance to A roads and motorways using maternal postcode at delivery,
- Ministry of Housing, Communities and Local Government information around Energy Performance Certificates (EPC) for building characteristics.

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

Confidential patient information requested

Cohort

All children born alive in England to English resident mothers between 01 January 2005 and 31 December 2014. There are 7 million children recorded in the existing sample. A sub-cohort of patients within this will be established for linkage with the 2011 Census which will include all births between March 2010 and March 2012.

The following items of confidential patient information held within the established birth cohort dataset will be used for the purposes described:

- Name (Mother) – linkage to 2011 Census information,
- NHS Number (Infant) – linkage to fully identifiable ONS birth registration data as part of linkage to Census,
- NHS Number (Mother) – within the birth cohort data set,
- Date of birth (Mother and Infant) – linkage,
- Date of death (Infant) – analysis,
- Date of death (Mother) – within the birth cohort data set,
- Postcode (birth) – linkage and analysis,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. It was recognised that exploring the impact of environmental factors on childhood hospital admissions was within the public interest. The Group recognised that the birth cohort which would be utilised in the study was already established via references PIAG 2-10(g)/2005 and CAG 9-08(b)/2014. A separate application for the proposed activity was appropriate due to the change in research purpose.

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 for the proposed activity due to the size of the birth cohort, containing seven million records, which would be used in the study. No issues were raised in this area.

- Use of anonymised/pseudonymised data

The CAG was assured that processing of confidential patient information was required in order to facilitate the linkage with the wider datasets to be used in the study, which could not be otherwise achieved. It was acknowledged that the Office of National Statistics was acting as a trusted third party to undertake the data linkage. Researchers would undertake analysis on a pseudonymised dataset made available in a secure environment. No issues were raised in this area.

Justification of identifiers

Members were assured that the items of confidential patient information requested were appropriate and proportionate to achieve the project aims. No issues were raised in this area.

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. Support under the Regulations was requested for the purposes of linkage only. A pseudonymised dataset would be created for analysis purposes. No issues were raised 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 applicant had consulted with the Parents' Advisory Group (PAG) at Great Ormond Street/UCL Institute of Child Health Biomedical Research Centre, Shelter and The British Lung Foundation during the course of the research design. Further work was planned via the Policy Research Unit for Children and Families (CPRU), funded by the NIHR. The CPRU will be setting up a new young people's advisory group who are specifically trained in research using administrative data sources, which be consulted with when established. The CAG was assured that the activity which had been undertaken in this area was appropriate and proportionate to the proposed activity and raised no issues in this area.

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 to objection and mechanism to respect that 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 2018. Members recognised the difficulties in establishing a meaningful communications strategy to support the project, due to the retrospective and national basis of the patient cohort to be included. The applicant had provided a draft notification document which would be placed on the UCL website in order to facilitate both the patient notification requirement under the common law duty of confidentiality and fair processing requirements in under current data protection regulations. Members commented that the document appeared appropriate to meet the local legal obligations; however, it was queried whether provision of the main applicant's direct email address was sufficient means of contact on the basis of the cohort size. The applicant would be asked to consider whether additional contacts could be provided and whether a generic contact may be more appropriate.

Members were unclear from the information provided how any patient objection would be managed if received and it was agreed that further information would be requested from the applicant to explain the mechanism for respecting dissent.

The Group agreed that there were wider opportunities which could be utilised in order to promote the study more widely. It was recognised that the applicant had established links with third sector organisations, including Shelter and the British Lung Foundation. Members recommended that an approach was made to these organisations to explore whether the project could also be promoted via these networks. It was also commented that the applicant could explore with patients and the public, as part of the wider activity which is planned in this area, to seek views on how the communications strategy for the study could be improved. The applicant would be asked to consider these comments and provide an overview of how wider promotion of the study would be achieved.

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.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for further information (Summary)

1. Consider whether provision of a single direct email contact with the patient notification material is appropriate, accounting for the size of the cohort to be included in the study. Provide a revised document if deemed appropriate detailing wider means of communication.
2. Clarify how the objection mechanism would be operated for the study, explaining how any dissent raised would be respected.
3. Provide an overview of how a wider communications strategy can be implemented in order to raise the profile of the study more widely in the public arena. It is recommended that established links referenced within the application, with Shelter and the British Lung Foundation, could be drawn upon to promote the study more widely.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed 05 October 2018**).
2. Confirmation from the IGT Team at the NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Office for National Statistics has a published satisfactory reviewed grade on V14.1, 2017/18**).

c. 18/CAG/0160 – Administering Cryoprecipitate in Obstetric Bleeding at an Earlier Time

Context

Purpose of application

This application from Queen Mary University of London set out the purpose of medical research which aims to assess the feasibility of administering cryoprecipitate early (within 90 minutes of major haemorrhage protocol activation) in pregnant women who are actively bleeding and who require blood transfusion within 24 hrs of delivery. This will be compared to standard treatment, where cryoprecipitate is given later or not at all. There will be four participating sites within the study and randomisation will occur at site level (cluster randomisation). The intervention group will deliver cryoprecipitate within 90 minutes to any women who meet the edibility criteria. The control arm will continue to give cryoprecipitate in response to low fibrinogen level or if they have received massive transfusion, defined as greater than eight units of red blood cells. The study will be fully unblinded to participants, clinical staff and the central research team.

Consent will not be sought for inclusion in the study as both care pathways involve a standard of care treatment. Routine baseline and clinical information will also be collected from all women who fulfil study criteria up to hospital discharge, or 28 days post-delivery (whichever is sooner). The application has been submitted to the CAG for consideration of the data collection processes to support this part of the study. Patient records will be accessed by member of the research team, who are not considered part of the direct care team, in order to identify patients who are eligible for participation in the trial and to undertake extraction of relevant information for analysis.

Every effort will be made to identify and approach eligible women for informed consent before discharge, to inform them why and how they have been treated as part of the study, and to allow them to opt out of data collection if they wish. Collection of de-identified routine data will only be used as a last resort, and the research team will need to document attempts made to contact the patient and reasons for not obtaining consent.

There are further future elements to the study which will be undertaken on a consented basis which will include collection of outcome data at three months, MFI Questionnaire, qualitative interviews and collection

of residual blood samples from hospitals. These are out of scope for the CAG consideration as patients will consent to these elements.

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

Confidential patient information requested

Cohort

Pregnant women at greater than 20 weeks gestation who are actively bleeding after childbirth (up to 24 hrs), and for whom major haemorrhage protocol has been activated, and/or transfusion of at least one unit of red blood cells has been started for treatment of bleeding. 200 patients will be recruited to the study across the two participating Trusts.

The research team would have access to complete patient records of all women who deliver at the participating sites in order to identify those patients eligible for inclusion. The following items of confidential patient information are required for the purposes of sample validation:

- Name,
- NHS Number,
- Hospital ID Number,
- Date of birth,
- Date of death,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose which was medical research. Members agreed that there was a public interest in the research proceeding as this was a life-threatening condition and the study would investigate whether there was a preferred treatment.

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 had explained that as only a limited number of women would be affected by the condition following labour (between 2-4%), it was not practicable to seek consent from all pregnant women due to deliver at the research sites to the size of this cohort. The Group accepted this rationale as it was recognised that the number of women who would give birth at the participating sites would be significantly more than the number of individuals who would suffer a major post-partum haemorrhage.

It was further explained that seeking consent at the point the major haemorrhage protocol was instigated was not feasible due to the potential for distress caused to the patients and the overarching importance of administering urgent clinical care. The CAG recognised the critical nature of care being provided and was assured that it would not be feasible to introduce a consenting procedure at this point.

The Group commented that the only data which would be collected for the study would be standard clinical information which would be available from the patient's medical record. Patients would only become participants in the study at the point data extraction from medical records commenced. As the required information was already recorded as part of standard care, it was unclear why data extraction could not be

undertaken retrospectively. It was stated in the application that women would be approached for consent to their involvement in the study prior to discharge from hospital. Members were unclear why the data collection process could not be delayed until after this point. As this was a rare occurrence, a limited number of patients would need to be approached for consent. The CAG agreed that the application did not provide sufficient justification to support the requirement for data collection to be undertaken before a patient could be approached for consent. On this basis, Members agreed that they were unable to provide a recommendation for the proposal and this would be deferred pending further information from the applicant. Should a revised application be submitted to the CAG, a stronger rationale was required to support the necessity for data collection to be undertaken before consenting patients to their involvement in the study.

The application cited the requirement for complete case ascertainment within the study, due to the limited number of women who would suffer a major post-partum haemorrhage. The CAG recognised that, due to the limited patients within this cohort, complete case ascertainment was important for the study analysis. However, Members noted that the application did not address the potential sub-cohort of patients who may die during the course of treatment. The Group agreed that any revised application would need to clearly set out the methodology in relation to deceased patients.

- Mental Capacity Act 2005

At Q7 of the application filter page, it had been stated that the project would include adults who lacked capacity to consent for themselves. The Mental Capacity Act 2005 (MCA) provides a comprehensive framework for decision-making on behalf of adults who permanently or temporarily lack the capacity to consent for themselves, including decisions to include such people in research. As the application identified that the patient cohort to be included in the study involved adults which lacked capacity to provide consent, it was unclear why the provisions established under the MCA were not being implemented as a practicable alternative to seeking support under the Regulations to legitimise the data processing within the study. The Group agreed that further information would be required as part of any revised application to justify why the research could not be carried out utilising the established MCA framework.

- Use of anonymised/pseudonymised data

Confidential patient information was not required for the purposes of the study analysis. In the current methodology, support had been requested to support access to medical records by the research team in order to extract the required data. Members acknowledged that processing of confidential patient information had been limited in the course of the study design and would be deemed appropriate, should a revised application provide a sufficient justification for timeliness of proposed data collection.

<u>Justification of identifiers</u>

The CAG noted that the applicants had not requested access to patient postcode. It was queried whether there would be merit in including the patient's deprivation score, derived from postcode, within the analysis. Members recognised that the issues relating to the science and analysis of a research project were the domain of the Research Ethics Committee; however, it was agreed that this query would be added to the outcome for the applicant's information only. No issues were raised with the items of confidential patient information which would be accessed.

<u>Patient and Public Involvement and Engagement</u>

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 trial was heavily linked with Katie's Team, the East London women's health patient and public advisory group. It was agreed that the activity in this area appeared appropriate and the future planned work was recognised. No specific queries were raised in this area as it was acknowledged that activity was planned to progress together with the 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 to objection and mechanism to respect that 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 2018. Posters would be displayed within the maternity units of participating maternity units in order to raise the profile of the research activity which was being undertaken. Information sheets and consent forms were also provided, which would be given to the relevant women following treatment for a major post-partum haemorrhage.

Members considered the drafts of the patient-facing documentation which had been provided. It was commented that the information sheet was unclear in its explanation that data would have been collected prior to the approach for consent and what would be involved should the patient consent to participate in the study. The Group agreed that, should a revised application be submitted for consideration, the patient information materials would require revision to clearly explain what activity had been undertaken prior to the approach for consent and what subsequent participation would entail.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation and Data Protection Act (DPA) 2018. The information which had been provided at Q57 was received, in relation to compliance with the Data Protection Act 1998 was received; however, the DPA 1998 had now been superseded. Further information would be required as part of any revised submission to explain how the proposed activity was compliant with GDPR Article 5(1) – principles (a)-(f). Specific confirmation was required around the lawful basis of processing data and special category data (principle A).

Research Ethics Committee (REC) 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 Group agreed that assurance was required from the reviewing REC that they were supportive of the proposed study methodology. It was agreed that a copy of any formal correspondence (provisional or favourable opinion letters) should be provided as part of any revised submission to provide assurance to 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

The following information should be provided to allow the CAG to continue their consideration of the application. A detailed covering letter should be provided advising how the below points have been addressed, together with a revised application form and supporting documentation.

1. Further consideration should be given to undertaking data extraction on a retrospective basis, to enable the project to progress of a fully consented basis. If this is not deemed to be feasible, a stronger rationale would need to be provided to justify the necessity to collect the pseudonyised data required for analysis, prior to approaching women for informed consent.
2. Further consideration should be given to the provisions of the Mental Capacity Act 2005 (MCA) and the potential for a practicable alternative to seeking support under the Regulations to be established within this framework. If it is determined that the MCA does not provide an appropriate framework to include patients within the study, a clear explanation would need to be provided as part of the revised application to support this.

3. The application should clearly address the methodology in relation to the patients who die during the course of their treatment, explaining how these individuals would be included in the study.
4. Patient information materials would need to be revised as part of the resubmission, to ensure a clear explanation was provided around what study interventions (including data collection) had been undertaken prior to the approach for consent and what consented participation would involve moving forward.
5. Provide copies of any formal correspondence from the reviewing REC for consideration.
6. The response provided at Q57 of the CAG application form should be updated to show compliance with GDPR Article 5(1) – principles (a)-(f) – further information can be found within the IRAS system by selecting the green 'I' icon next to the question.

For Information only:

The following point has been added for the applicant's information only and does not need to be specifically addressed as part of any revised application:

1. Consideration should be given as to whether accessing patient postcode, in order to calculate index of multiple deprivation scores, would have any merit for the research analysis.

d. 18/CAG/0162 – ECG Parameters predicting Adverse Events in Congenital Heart Disease

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research which aims to investigate whether there is a way to predict which children and adults who have previously undergone surgery for congenital heart disease are at higher risk of developing abnormal heart rhythms (arrhythmias), including ventricular tachycardia (VT), ventricular fibrillation (VF) and sudden cardiac death. This is a retrospective record review only. Records from the congenital heart disease database at the Freeman Hospital, Newcastle upon Tyne Hospitals NHS Foundation Trust, will be accessed in order to extract a pseudonymised dataset to be used in the study analysis.

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

Confidential patient information requested

Cohort

Male and female patients, who underwent surgery at Newcastle upon Tyne Hospitals NHS Foundation Trust to treat congenital heart disease. Between 50 and 150 patients will be included in the study analysis.

Access to the complete medical records is required. The following items of confidential patient information are required for the purposes described:

- NHS Number – linkage,
- Date of birth – analysis,
- Date of death – analysis,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members commented that the sample size had not been justified within the application and it was noted that between 50 and 150 patients could be included in the study. The Group was unclear from the information provided whether the proposed sample could produce sufficient data to facilitate meaningful analysis. It was agreed that further information was required around these statistical elements to ensure there was a justified public interest in the application activity proceeding.

Following the consideration of the application at the CAG meeting, the Confidentiality Advice Team (CAT) received a copy of the provisional ethical opinion from the reviewing Research Ethics Committee. It was noted that the REC had requested that the statistical aspects of the project and methods of analysis of the results were reviewed by a statistician as part of the request for further information within this provisional opinion. If this statistical review also addressed the concerns which had been raised by the CAG, this information would be welcomed within the response to the CAG to provide justification of the public interest in the activity proceeding.

Cohort

Further information was required to define the patient cohort which would be included in the study. Whilst it was recognised patients would be retrospectively identified from the congenital heart disease database, the eligible timeframe for inclusion in the study had not been identified. It was also unclear how many patient records would be screened in order to identify the patients which would be included in the study. The CAG agreed that further clarification was required around these points in order to clearly define the patient cohort which would be included in the study and the scope of support which would be required under the Regulations in order to identify this group.

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 recognised that consent was not feasible for the sub-cohort of deceased patients; however, was of the view that insufficient justification had been provided to support why consent was not feasible from living patients. It was noted that this patient group would have ongoing clinical follow-up which would present an opportunity to approach for consent. The Group agreed that further information was required from the applicant to justify why consent was not feasible for the proposed activity. On this basis, it was confirmed that a recommendation for the proposed application would be deferred, pending submission of further information.

- Data Extraction by the Direct Care Team

The application explained that data extraction would be undertaken by members of the direct care team and student researchers. It was noted that analysis would be undertaken on a pseudonymised dataset only. A justification had not been provided within the application to support why the data extraction process could not be managed solely by the direct care team as a practicable alternative to seeking support under the Regulations. The applicant would be required to consider this potential way forward – if it was determined that this was not a feasible alternative to seeking support under the Regulations, a strong justification would be required to support this decision as part of any revised application.

- Use of anonymised/pseudonymised data

Access to confidential patient information was required to establish the patient cohort for inclusion in the study and to facilitate linkage with wider medical records, which could not be otherwise achieved. It was stated that analysis would be undertaken on a pseudonymised dataset only; however, the CAG agreed that assurance would be required that date of birth and death, which were cited as necessary for analysis, would not be disclosed in a complete format.

Justification of identifiers

The Group were assured that the items of confidential patient information requested were appropriate and proportionate to achieve the proposed activity. No issues were raised in this area.

Transfer of Data

Members expressed some concern around the proposed method of data transfer between the Trust and the University, which would be undertaken via encrypted USB drive. It was queried whether it would be possible to transfer data via secure email transfer, rather than physical storage device to increase security. This would need to be addressed as part of any revised application.

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. Analysis would be undertaken on a pseudonymised dataset only; however, it was unclear at what stage this would be carried out. It was agreed that any revised application should provide a clear timeframe around when pseudonymisation would occur.

It was stated within the application that the pseudonymisation linkage key would be retained for three years and would be accessible to both members of the direct care team and student researchers. Members were unclear why it was necessary to maintain the linkage for this duration of time and agreed that further information would be required as part of any revised submission to justify this ongoing retention. It was further commented that, should the retention of the linkage key be appropriately justified, access to this should be limited to members of the direct clinical team to prevent the ongoing requirement for support under the Regulations. If access to the key by student researchers was a necessity, appropriate justification to support this requirement would be required as part of the revised application.

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. No activity had been undertaken or was planned in this area. Members commented that patients who had undergone surgery for congenital heart disease would be in regular clinical follow-up. As an active patient population, there would be opportunities to approach patients and their families within clinics about the study. The Group agreed that further work was required from the applicant's in this area in order to test the acceptability of using confidential patient information without consent for purposes of the study, in order to support the public interest in the activity proceeding. Feedback should be provided as part of any revised submission around activity which has been carried out. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, 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 to objection and mechanism to respect that 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 2018. The application did not describe

any means of promoting the study in the public arena in order to raise the profile of the proposed activity and offer a mechanism to enable patients to dissent to the use of their data. The Group agreed that a communications strategy, together with copies of any documentation which would be used to facilitate promotion, would need to be described as part of any revised application.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation and Data Protection Act (DPA) 2018. The information which had been provided at Q57 was received, in relation to compliance with the Data Protection Act 1998 was received; however, the DPA 1998 had now been superseded. Further information would be required as part of any revised submission to explain how the proposed activity was compliant with GDPR Article 5(1) – principles (a)-(f). Specific confirmation was required around the lawful basis of processing data and special category data (principle A).

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 Newcastle upon Tyne Hospitals NHS Foundation Trust had been published in respect of version 14.1 (2017/18) 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.

Other Points

It is a mandatory requirement that a letter of recommendation from the Caldicott Guardian, or organisational equivalent, is provided to support an application for consideration by the CAG. This document was omitted from this proposal and would be required as part of any revised submission. The applicant would be reminded to submit copies of all mandatory documents as listed in the CAG checklist within the IRAS system

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

The following information should be provided to allow the CAG to continue their consideration of the application. A detailed covering letter should be provided advising how the below points have been addressed, together with a revised application form and supporting documentation.

1. Further consideration should be given to taking consent from living patients within the eligible cohort for their inclusion in the study. If it is determined that this is not feasible, a stronger rationale should be provided as part of a revised submission to justify this decision.
2. Further consideration should be given to the data extraction process being managed solely by the direct care team as a practicable alternative to seeking support under the Regulations. If it is determined that this is not feasible, a stronger rationale should be provided as part of a revised submission to justify this decision.
3. Confirm the sample size required to enable the study analysis to be undertaken, providing justification to support the proposed sample. Assurance is required that the sample size is sufficient to enable meaningful study analysis to be undertaken, in order to establish a public interest in the activity proceeding.
4. Provide a clear overview of the patient cohort to be included in the study including the eligible timeframe for sampling.

5. Confirm how many patients' records would be screened in order to establish the eligible cohort for inclusion.
6. Confirm what information would be included in the pseudonymised dataset extracted for analysis. This should clarify in what format dates of birth and death would be transferred.
7. Provide a clear overview of the pseudonymisation process, clarifying the anticipated timeframe for this to be achieved.
8. Consider whether data could be transferred between the Trust and University via secure email exchange to prevent the use of physical storage devices, i.e. USB sticks – confirmation of the proposed transfer methodology should be provided as part of a revised submission.
9. Justify the proposed retention of the pseudonymisation linkage key for the stated three year duration. Confirm that access to this key would be limited to the direct care team only. If ongoing access to the key is necessary for student researchers, a strong rationale would be required to support this.
10. Activity should be undertaken to seek the views of an appropriate group of patients and the public around the proposed use of confidential patient information without consent for the study purposes, in order to test the acceptability of this proposal. Detail should be provided around the activity which has been undertaken, the group which was approached together with the feedback which was provided. If the responses given are negative, the CAG would take this into account when considering whether support can be recommended or whether further information is required.
11. A communications strategy to raise the profile of the proposed activity in the public domain should be devised, to include a mechanism for patients to object to the use of their data for these purposes. Details of how and where the study would be advertised would be required, together with an overview of how an objection mechanism would be operated. Copies of any documentation which would be used to facilitate this system would be required for review.
12. The response provided at Q57 of the CAG application form should be updated to show compliance with GDPR Article 5(1) – principles (a)-(f) – further information can be found within the IRAS system by selecting the green 'I' icon next to the question.
13. Ensure the revised application is supported by copies of all documents listed as mandatory within the CAG applicant's checklist within the IRAS system.
14. Confirmation of NHS Digital's review of Newcastle upon Tyne Hospitals NHS Foundation Trust's NHS IG Toolkit submission is required – this can be followed up directly with NHS Digital by contacting the Exeter Helpdesk (exeter.helpdesk@nhs.net). The element would need to be in place prior to any final recommendation of support coming into effect; however, does not need to be satisfied in advance of submitting a revised application for review.

5. MINUTES OF THE MEETING HELD ON 06 SEPTEMBER 2018

Review and approval of the minutes from the meeting held on 06 September 2018 were deferred pending resolution of the outstanding application outcomes.

6. CAG CHAIR REPORT

Members received a report from the Chairman for September 2018.

7. ANY OTHER BUSINESS

No further business was raised. The Chair thanked Members for their time and the meeting was closed.