Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

15 November 2018, Barlow House, 4 Minshull Street, Manchester, M1 3DZ

Present:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Dr Patrick Coyle	Yes	Vice Chair
Professor Barry Evans	Yes	
Dr. Liliane Field	Yes	
Dr Lorna Fraser	Yes	
Mr Anthony Kane	Yes	Lay Member
Mr Andrew Melville	Yes	Lay Member
Ms Clare Sanderson	Yes	
Dr Murat Soncul	Yes	Alternate Vice-Chair
Ms Gillian Wells	Yes	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Internal Observer
Miss Kathryn Murray	Senior Confidentiality Advisor

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

The Chair welcomed Miss Katy Cassidy to the CAG meeting. It was noted that Ms Cassidy has recently been appointed to the Confidentiality Advisor post within the Confidentiality Advice Team and would be commencing this new role from December 2018.

The following conflicts of interest were raised at the meeting:

- **Agenda Item: 4.b – Application 18/CAG/0180**

Dr Lorna Fraser declared as conflict of interest with this application. The CAG agreed that Dr Fraser could remain during discussions, but could not participate is the deliberation or recommendation against the application.

- **Agenda Item: 4.d – Application 18/CAG/0184**

The CAG noted that Dr Rachel Knowles, CAG Member, was named as a co-applicant on the application. It was agreed that this would be noted in the minutes and outcome letter in the interests of transparency.

2. APPROVAL DECISIONS

Secretary of State for Health and Social Care Approval Decisions

There were no non-research applications considered at the CAG meeting held on 18 October 2018.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 18 October 2018 meeting applications.

3. RESUBMITTED APPLICATIONS

a. 18/CAG/0187 (Previously considered as an amendment to ECC 1-05(b)/2012) – Avon Longitudinal Study of Parents and Children (ALSPAC) Generation 0 Parent/Carers: Linkage to routine health records

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research which aims to follow-up the parents and carer cohort (referenced as Generation 0 within the application) of the Avon Longitudinal Study of Parents and Children (ALSPAC) study via NHS administrative datasets held by NHS Digital, together with records held at local Trusts and primary care data from GP practices.

The Avon Longitudinal Study of Parents and Children (ALSPAC) is a three-generation cohort study with >15,000 enrolled participant families. Comprising the G0 generation cohort of pregnant women who lived in Bristol in 1991/92 and the fathers/partners; the G1 generation of children born in 1991/92 cohort; and the G2 generation of G1 offspring. All generations have provided information in questionnaires, study clinic assessments, through gifting biological samples and linkage to routine records. To obtain ALSPACs full value further follow–up is needed to explore research questions relating to the G0's health and wellbeing as they age and to investigate how exposures to G0 parent/carers interactions with the long-term outcomes in G1. Extending linkage to health records provides a cost-effective means of data collection with low participant burden.

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

Confidential patient information requested

Cohort

All parents and carers originally recruited to the ALSPAC study, known as 'Generation 0'. There are approximately 15,500 patients in this cohort.

The following items of confidential patient information are requested for the purposes identified:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Hospital ID Number – sample validation and linkage,
- GP registration – sample validation and linkage,
- Date of birth – sample validation and linkage and analysis,
- Postcode – sample validation and linkage and 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. The Group acknowledged that ALSPAC was a longitudinal research programme, the strength of which was the inclusion of and interaction between the multigenerational cohorts. Members were assured that there was a public interest in extending the data linkage to the Generation 0 (G0) cohort of parents and carers of the ALSPAC birth cohort.

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 the original ALSPAC study had operated on a consented basis; however, it was assured that re-consenting patients for the purposes of the data linkage follow-up was not feasible due to the size of the cohort and the potential for bias within the sample.

It was noted that the applicants had provided some evidence to support why seeking consent was not feasible which related to a previous follow-up study. Members were unclear from the information provided whether the applicants had previously contacted the G0 cohort to seek consent for the proposed data linkage activities. It was noted that support under the Regulations could not be sought to provide a legal basis for processing in respect of an activity for which explicit consent had been sought. The Group agreed that confirmation would be sought from the applicant that they had not historically attempted to consent the patient cohort for the proposed data linkages. If is confirmed that there has been no previous attempt to consent the cohort for this specific activity, this would need to be accurately reflected in the supporting documentation. Members noted the GP letter as specific example, as this document suggested that patients had been approached on multiple occasions to provide consent, which did not appear to be an accurate reflection of the situation.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate linkage with the wider clinical datasets which could not be otherwise achieved. 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. It was recognised that the ALSPAC programme was a longitudinal research programme, which proposed linkages with clinical datasets on an annual basis to follow-up patients over time. As such, a definitive exit strategy had not been established for the complete programme.

The application described an ongoing programme to seek consent from patients, as part of a clinical assessment, for the record linkage component. It was unclear from the information provided whether this activity was seeking formal consent, as the patient-facing documentation which had been provided was actively promoting the right of objection, rather than seeking consent from patients. The importance of the terminology used was reiterated due to the potential for future activities to be limited due to a decline or lack of response to a formal consenting request. The Group agreed that further information was required from the applicant around this activity to clarify what approach was being made to patients. It was reiterated that, if a patient was formally asked to consent to an activity and either declined, or did not respond, support under the Regulations could not be sought for this activity. The Group further commented that consent could not be taken retrospectively for data processing which had already occurred, but could only be sought for the onward retention of the linked data.

Cohort

Members considered the detail provided at Q25 of the application form around the study cohort. It was noted that there were 20,000 eligible pregnancies at the time of the original ALSPAC recruitment, of which approximately 14,500 mothers enrolled in the study. It was then stated that a further 1,000 participants had since been enrolled. The CAG was unclear who this additional sub-cohort of participants was and how they were recruited. It was noted that there was a reference to an academic journal which had been submitted alongside the wider application; however, the Group agreed that clarification was required directly from the applicants to understand if these additional participants were included in the scope of the request for support being considered.

Scope of Support

The remit of the CAG is defined in section 251 of the NHS Act 2006 and its Regulations. Information that falls within the scope of Regulation 5 of the COPI Regulations is set out in the NHS Act 2006 and states it must firstly be ‘patient information’, which is defined at (s251(10)) and then ‘confidential patient information’ which is defined at s251(11). The Group recognised that, as with the recently supported amendment in relation to the G1 cohort, some of the information referenced in the application form clearly would not fall within the scope of these legal definitions and for these, support could not be provided. Marriage certificates were cited as an example from the dataset described which would not fall within the definition of confidential patient information.

The Group was content to provide a recommendation of support to the access and linkage with the registry data and personal demographics information held by NHS Digital which was cited within the application form. Support was recommended on the basis that the remit of the CAG extended to information which fell within the definition of confidential patient information only. Members were clear that it would be the responsibility of the applicant, together with NHS Digital as the controller for the data sets, to determine which information fell within this definition and establish an alternative legal basis in relation to the processing and disclosure of information which fell outside of this definition.

Linkage with Sensitive Datasets

The applicant had acknowledged within the submission the specific conditions of support which were attached to the linkage activities for the generation one (children) cohort. In particular, it was noted that access to sensitive data fields was not permitted as part of the recommendation of support given. Any access to sensitive data fields, such as those pertaining to sexual or mental health, artificial reproduction and physical, mental or sexual abuse should be submitted as an application in its own right, with supporting ethical approval. It was noted within the application that the determination around which data items would fall into this sensitive classification would be determined by ALSPAC which the Group did not think was appropriate. It was reiterated that any application seeking to use the types of data described would need to be submitted for independent consideration. A specific condition of support would be attached to the approval to address this point.

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 recognised that overarching ALSPAC programme was underpinned by extensive patient and public involvement and engagement activities. Members were impressed by the continuing commitment to include the views of patients and the public in the research programme and raised no queries 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 that the applicant had maintained channels of communication with the cohort since in the initial study commenced in the nineties. The information provided to support the application was clear and informative, making clear the right to opt-out. The Group raised no issues in this area and commended the communications strategy which underpinned the programme.

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 scores for North Bristol NHS Trust, Weston Area Health NHS Trust and Royal United Hospital Bath NHS Trust, had been published in respect of version 14.1 (2017/18) of the toolkit; however, these self-assessments 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

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. Clarify whether there has been any historic approach to consent participants for the proposed data linkage. If not, supporting documentation should be revised to ensure the terminology accurately reflects any attempts to contact patients.
2. Provide further details around the referenced prospective consent programme to clarify whether this approach was intended to be a formal consenting programme.

3. Further information is required around the additional 1,000 patients who have been recruited to the study since initial enrolment. Provide further information around who this group is and how they were recruited, together with clarification around whether this sub-cohort is also included within the scope of support requested via this application.

Specific conditions of support (Provisional)

1. Support extends to the linkage and access to confidential patient information held within the registry datasets and personal demographics information cited in the amendment application. Support does not extend to those items/data sources that are not clearly confidential patient information. It is the responsibility of the applicant, together with NHS Digital, to determine which of the specific data items requested would fall within the legal definition set out in the NHS Act 2006. An alternative legal basis would need to be established for information which does not fall within the legal definition set out in the NHS Act 2006.
2. Access to sensitive data fields, such as those pertaining to sexual or mental health, artificial reproduction and physical, mental or sexual abuse, is not supported under this application. Any requirement to link to these sensitive data field should be submitted as an application in its own right for review by the CAG and a NHS REC.
3. Favourable opinion from a Research Ethics Committee (**Confirmed – 31 August 2018**).
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending:**

- **ALSPAC, NHS Digital and University Hospitals Bristol NHS Foundation Trust: published satisfactory reviewed grades on V14.1, 2017/18,**
- **North Bristol NHS Trust, Weston Area Health NHS Trust and Royal United Hospital Bath NHS Trust: self-assessed scores on V14.1, 2017/18, which have not been reviewed by NHS Digital,**
- **GP Practices – not requested for each site due to numbers; however, support is recommended on the premise that the applicant will ensure that satisfactory security assurances are in place for each site.**

4. NEW APPLICATIONS

a. 18/CAG/0188 – Road Traffic Injury – Analytics for Integrated Data (RTI-AID)

Context

Purpose of application

This application from Imperial College London set out the purpose of medical research which aimed to investigate the patterns of physical trauma caused amongst individuals suffering road traffic accidents in order to identify risk factors for injury severity. The project will use Greater London as a representative population of the UK. The project will link datasets from the London police, transport and health systems in order to create a database which follows individuals involved in road traffic accidents from the point of impact to indefinite care in order to facilitate analysis of patterns of risk and injury behaviour.

The study will link information from the following sources:

- STATS19 accident data – police accident reporting form (out of scope for CAG),
- Trauma Audit Research Network (TARN) – which operates with support under the Regulations under reference ECC 7-05(g)/2011,
- London Ambulance Service (LAS),
- Hospital Episode Statistics (HES).

To limit access to confidential patient information, data will be disclosed from the providers direct to NHS Digital, which will act as trusted party for the project, facilitating linkage with the HES dataset, prior to disclosing a pseudonymised dataset to the applicants at Imperial College London to be utilised for analysis.

The project will also link the data from these established data sources with novel datasets including Transport for London Public API, Waze traffic app, news feeds, Twitter posts. This supplementary information is available within the public domain and is out of scope for CAG consideration.

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

Confidential patient information requested

Cohort

All individuals who were involved in a road traffic collision and road traffic collision in the Greater London area between 2013 and 2017 featured in the datasets prescribed (STATS 19, LAS, HES, TARN). It is estimated that there will be 5,000 patients within the cohort.

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

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Hospital ID No – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Date of death – sample validation, linkage and analysis,
- Postcode – sample validation and linkage,
- Sex – analysis,
- Ethnicity – linkage 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 were unclear around what overarching public interest would be achieved by the project. It was recognised that the relevant controllers had been engaged in the project from an early stage, which supported that the key stakeholders were confident that the linkage could be achieved. However, the Group had concerns around the potential limited success of the fuzzy matching linkage process. As issues pertaining to the science of research proposals were the remit of the REC to assess, the CAG agreed that feedback from the REC review of the application would be required to provide assurance in this area.

The applicant had explained that the overarching aim of the project was make recommendations for changes in clinical practice and public health and safety policy. Members commented that the public health focus of the proposal was unclear. As the application had not been submitted as a feasibility study with the aim of testing the viability of the data linkage, it was agreed that further information would be requested from the applicant to understand how the dataset would be used for patient benefit.

Scope of Support

The remit of the CAG is defined in section 251 of the NHS Act 2006 and its Regulations. Information that falls within the scope of Regulation 5 of the COPI Regulations is set out in the NHS Act 2006 and states it must firstly be ‘patient information’, which is defined at (s251(10)) and then ‘confidential patient information’ which is defined at s251(11). The STATS19 accident data did not fall into the scope of these legal definitions. The applicant provided agreement to this position, confirming an alternative legal basis existed to support this disclosure.

The dataflow chart provided with the application identified disclosure of information from the London Ambulance Service (LAS) to NHS Digital as within the scope of the request for support under the Regulations. Members were unclear what information would be disclosed from LAS and whether this would

fall within the scope of the legal definitions of the CAG's remit to advice. This query was raised as it appeared from the dataflow chart that the information released by LAS would only be subject to the fuzzy matching process based on location, time and gender. The Group agreed that clarification was required around what data would be released by LAS together with justification of how this fell within the scope of the legal definition of confidential patient information.

Cohort

The CAG noted discrepancy around the inclusion timeframe for the project. Clarification would be sought around the specific start and end dates for the sample.

Members queried whether the TARN network would be disclosing information in relation to adult patients only, or whether children would be included in the sample. This point would also be clarified with the applicant.

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 applicant had stated that consent was not feasible due to the size of the retrospective patient cohort which would be included in the study. Whilst Members were assured by this justification, it was commented that a stronger rationale could have been made. The Group noted that it was likely that a proportion of the cohort would be deceased and also that the operation of a consented model would require a more significant breach of patient confidentiality. The CAG was assured that consent was not feasible for the project.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate linkage between the various sources which could not be otherwise achieved. It was recognised that access to confidential patient information had been limited within the overall methodology as NHS Digital was acting as a trusted third party to facilitate linkage. No issues were raised 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. The CAG noted discrepancies between the information included within the dataflow chart, which stated that linkage would be facilitated on NHS Number alone, and the detail included Q37 of the application form, which listed a considerable number of identifiers which would be used to facilitate the linkage process. The applicant would be asked to clarify exactly which items of confidential patient information would be released from each data source to NHS Digital to facilitate the linkage process.

It was further noted that date of death was required for analysis purposes. Members were unclear in what format this was required for analysis, as it was recognised that the resulting dataset would not be pseudonymised if this identifier was provided in true format. It was also suggested that fact of death may be sufficient for the project analysis. Clarification was required around this point – it was commented that if date of death was required in a true format, a scientific justification would be required from the applicant to support this.

Data Flows

The Group was unclear where and by whom the novel linkage with wider data sources, like Twitter as example, would be taking place. It was also unclear at what stage within project timeframe this would be carried out in relation to the wider linkage being undertaken by NHS Digital. Members agreed that further information was required around this supplementary data linkage, due to the risks around re-identification. Clarification would be sought prior to any recommendation of support coming into effect.

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 understood that NHS Digital would retain confidential patient information for a period of 12 months following linkage, to ensure the linkage is successful.

Members considered the information provided at Q54 of the application form, which suggested that the applicants would be retaining raw data as well as pseudonymised record level data. The Group was not clear around the distinction between the two datasets as it was understood that the applicants were only being provided with pseudonymised data for analysis. Further information was required from the applicant to explain what data would be retained.

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 significant activity had been undertaken in this area, engaging patients and the public and other wider stakeholders in the application process. It was noted that further work was planned with patient and public representatives as the study progressed in order seek views around how disseminate the research findings in an appropriate format. Members raised no concerns in this area; however, it was suggested that the dissemination of the research findings should be widened to ensure the benefit from the project was maximised.

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 considered the information provided around the communications strategy for the project. It was recognised that information would be provided on NHS Digital's website, the University website together with a project-specific website which would go live once all permissions were in place. Members were satisfied with the wider communications strategy for the project.

The applicant had advised that a project-specific dissenting mechanism could not be operated for the project. The Group recognised the challenges which presented in establishing an objection mechanism for an activity where the main applicant will not have access to confidential patient information; however, it was commented that further channels could be explored to facilitate this. Members suggested that the TARN network could be approached around the potential of promoting the study via their website and also facilitating a study-specific dissenting mechanism within the data it held. The applicant would be asked to progress this option to see if this was a feasible avenue for operating a meaningful notification and objection mechanism.

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. Provide further information around the analysis which would be undertaken on the linked database to explain how this would be used to improve public health.
2. Outcomes from the review by the Research Ethics Committee should be provided for consideration.
3. Clarify what information would be released by the London Ambulance Service to NHS Digital and confirm how this falls within the scope of the definition of confidential patient information.
4. Provide a definitive list of items of confidential patient information which would be released by each organisation to NHS Digital for the purposes of linkage. Discrepancies between the application form and the dataflow chart should be addressed.
5. Confirm whether date of death or fact of death alone is required for the study analysis. If date of death is required in true format, a scientific justification should be provided to support this.
6. Confirm the specific start and end dates for the inclusion timeframe for the study (DD/MM/YY format).
7. Clarify whether the TARN network will be releasing information on adult patients only or adult and child.
8. Provide further information around the linkage process with the novel datasets (i.e. Twitter) – clarification is required around who and where this linkage would be carried out and at what stage in the project timeframe in relation to the wider linkages.
9. Explain what information would be retained following the study, with specific reference to two datasets referenced at Q54 of the application (raw data/raw pseudonymised data).
10. The Trauma and Research Network should be approached around the potential of operating a project-specific dissenting mechanism for the study. Outcomes of the discussion should be provided – if is determined that this is not feasible, a strong rationale should be provided to support this. If this will be taken forward, copies of any supplementary patient-facing information would be required, together with an overview of how the dissenting mechanism would be operated.

Specific conditions of support

1. Ways to widen the dissemination of the research findings should be explored to ensure the benefits of the project are maximised and the appropriate agencies are aware of the outcomes. Feedback should be provided at the time of annual review of progress made with the dissemination plan.
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 – NHS Digital is acting as data processor for the study and has a published satisfactory reviewed grade on V14.1, 2017/18).**

b. 18/CAG/0180 – LAUNCHES QI - Linking Audit and National datasets in Congenital Heart Services for Quality Improvement

Context

Purpose of application

This application from University College London set out the purpose of medical research which aims to improve services for congenital heart disease and provide a template for other lifelong conditions by linking five national datasets to provide better information on services. The following datasets will be linked: National Congenital Heart Disease Audit (NCHDA), paediatric intensive care audit, (PICAnet), adult intensive care audit (ICNARC Case Mix Program), Office of National Statistics mortality information (ONS) and Hospital Episode Statistics (HES) data. This will provide information on how to link national data sets and whether it is feasible to do this routinely, and create a research database to examine the care given to CHD patients from multiple perspectives. The project will describe patient care trajectories; identify metrics

for driving quality improvement (QI), informing commissioning and policy; explore variation across services to identify priorities for quality improvement.

The audit datasets which will be linked within the application are as follows:

- National Congenital Heart Disease Audit – forms part of the NICOR (National Institute for Cardiovascular Research Outcomes) audit programme commissioned by HQIP. Barts Health NHS Trust are processors for the NICOR programme. This audit operates with support under the Regulations covered by application reference 17/CAG/0071 (previously ECC 1-06(d)/2011),
- Paediatric Intensive Care Audit – commissioned by HQIP. University of Leicester is the data processor. This audit operates with support under reference PIAG 4-07(c)/2002.
- Adult Intensive Care Audit – This audit operates with support under reference PIAG 2-10(f)/2005.

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

Confidential patient information requested

Cohort

Patients included within the national congenital heart disease audit. This comprises of all patients who have undergone at least one procedure related to congenital heart disease since 2000 up to March 2018. The sample includes 122,267 patients.

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

- Study ID – linkage,
- Name - sample validation and linkage,
- NHS Number – sample validation and linkage,
- Hospital ID Number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Postcode – sample validation and linkage, translated to IMD score for 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 recognised that there was potential for huge benefit from the wider understanding of patient care trajectories. The Group was assured that the proposed activity was within 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 applicant provided a number of sound arguments to support the determination that consent was not feasible for the project. It was noted that a number of datasets which would be linked within the project were collected without patient consent, with support under the Regulations, there was a requirement for complete case ascertainment which could be impaired by a consenting model as patients may be deceased or discharged from care and the potential distress caused by an approach for consent a

considerable time after treatment. On this basis of this rationale, Members were assured that consent was not feasible for this proposal.

- Use of anonymised/pseudonymised data

Confidential patient information is required to facilitate the linkage between wider datasets which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to undertake the proposed linkage activity. No issues were raised.

Exit Strategy

Support was requested to facilitate the data linkage process only – the applicant had stated that it was anticipated that the confidential patient information shared to facilitate this process would be deleted by June 2019. 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 CAG recognised the quality of activity which had been undertaken in this area. The applicants had been involved with the congenital heart disease community for over four years and it was explained that this project arose in part from the wishes expressed by families and patients for better information on the CHD patient journey.

It was further noted that there were two patient representatives within the project advisory group. Two further patient representatives would be involved as the study progressed. The applicants had also established links with key CHD patient charities, including Children's Heart Federation, Little Hearts Matter and Somerville Foundation, who will be kept updated with the study progress. The patient representatives and charity partners were supportive of the project and its methodology. Members were assured by the activity which had been undertaken in this area and raised no queries.

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 applicant advised that they were in discussions with NICOR to facilitate patient notifications and project-specific objections via its website. Members considered the text which had been provided and agreed that a telephone number and email address should also be provided as means to facilitate objection or correspondence.

The Group recognised the work which had been undertaken by the applicant to establish links with appropriate charities and it was commented that these existing relationships could be built on in order to promote the project more widely. Members agreed that the linked charities should be approached around displaying the information leaflet on their websites in order to widen the communications strategy for the project. Feedback would be 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

1. The patient notification text should be revised to include a telephone number and email address, in addition to the postal address, to facilitate dissent.
2. An approach should be made to the charities with which links were already established to explore the potential of including information around the study on their websites in order to widen the communications strategy for the project. Feedback should be provided around these discussions, together with copies of any text which would be displayed on the websites.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed: Barts Health NHS Trust (covering NICOR), University of Leeds (SEED – covering PICAnet), ICNARC (covering Case Mix Program) and NHS Digital – published satisfactory reviewed grade on v14.1, 2017/18**).

c. 18/CAG/0182 – UK Prospective Diabetes Study (UKPDS) Legacy Study

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to undertaken longitudinal follow-up participants within in the UK Prospective Diabetes Study (UKPDS). This original study ran from 1977 and 1997 and was extremely successful and demonstrated that important complications of type 2 diabetes can be prevented by better blood glucose and blood pressure control than that usually achieved, using existing treatments.

The researchers now wish to use this established resource to study the effect of blood pressure lowering and improved glucose control on reducing the risk of developing dementia later in life. Further analysis will also be undertaken to assess the effect of blood pressure lowering and improved glucose control on reducing the long-term risk of death, other important diseases e.g. heart attacks, strokes and kidney disease) and healthcare use.

Confidential patient information will be disclosed to NHS Digital in order to facilitate linkage with HES, ONS mortality information, the mental health minimum dataset (MHMD) and the dementia audit to be used in analysis. This will be linked to the existing UKPDS data held by University of Oxford for analysis.

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

Confidential patient information requested

Cohort

All patients previously enrolled in the UK Prospective Diabetes Study. There are 5,102 patients in the cohort. There are 4028 English patients within the sample.

Confidential patient information will be disclosed from the University of Oxford to NHS Digital to facilitate linkage. The following data items are cited as necessary for the purposes specified:

- UKPDS Study ID – linkage,

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Date of birth – sample validation, linkage and analysis,
- Date of death – sample validation, linkage and analysis,
- Postcode – sample validation and linkage,
- Sex – 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 clear public interest in utilising the established patient cohort to understand if blood glucose and pressure control also had an impact on the risk of developing dementia in later life.

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 by the applicant's justification around why consent was not feasible for the project. It was stated that attempting to follow-up patients by their GP with questionnaires would be costly and cumbersome and would likely lead to incomplete data due to the number of patients within the original cohort who were now deceased. It was also recognised that the consent which had been taken in the original study would not be considered valid for this wider data linkage.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage process which would be undertaken by NHS Digital and could not be otherwise achieved.

Justification of identifiers

The Group was assured that the items of confidential patient information requested were appropriate and proportionate to facilitate the data linkage. It was recognised that date of death was required for analysis; however, it was unclear in what format this would be disclosed to the applicants. Members suggested that this should be limited to month and year format. The applicant would be asked to confirm agreement to this, or provide a scientific justification to support the requirement for date of death in its complete format.

Data Flows and Linkage

Where support is recommended under the Regulations, this is proscriptive to the people, purposes, data flows and items. Any recommendation of support under this application extended to linkage with the HES, ONS and MHMDS datasets held by NHS Digital only. Members advised that should wider linkages become necessary, an amendment would need to be made to the application for consideration by the CAG.

It was recognised that the original study had recruited across the UK and whilst the remit of the CAG extended to England Wales only, it was noted the applicant had applied to the Public Benefit and Patient Privacy Panel in Scotland to undertake the same follow-up. The Group queried whether the applicant had considered how to manage cross border data retrieval, should patients have relocated to or from Scotland in the intervening period. This point would be queried with the applicant.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. Members acknowledged that four patient representatives had been involved in the trial design and had been consulted about the proposed activity.

It was also noted that the applicants had surveyed four key patient panels about the proposed activity and the feedback provided was largely supportive of this. The Group noted that in the overview of the feedback from this survey provided in both the application form (Q15-1) and the study protocol (Appendix C), there appeared to be some discrepancy in the responding figures, as the total sample sized interchanged between 34 and 35 participants, so it was unclear whether the reported percentages were accurate. The CAG noted that this was a minor discrepancy and didn't alter the overall outcome significantly.

Members were assured that the activity which had been carried out in this area was appropriate and proportionate to the proposed activity and raised no issues.

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 applicant had submitted a privacy notice as part of the application submission. It was confirmed that this document was intended to fulfil fair processing requirements in relation to data protection legislation and patient notification requirements in order to comply with the requirements of the common law duty of confidentiality. The information would be displayed on the University of Oxford's website.

Members recognised that facilitating a meaningful communications strategy for a historic patient cohort was difficult and were satisfied that displaying information on the University website appeared appropriate in this instance. The CAG commented that detail around the right to object was hidden in the document, which should be revised to make this information more prominent. It was also noted that the document did not clearly articulate that confidential patient information would be disclosed to wider NHS organisations in order to facilitate linkage. The Group agreed that the document would need to be revised 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

1. Date of death should be retained in MM/YY format only for analysis – provide agreement to this term, or provide a scientific rationale to support why this data item would be required in its complete format.
2. Clarify whether there has been any consideration of cross-border data retrieval, should any of the historic patients have relocated to or from Scotland in the intervening period.
3. The website text should be revised to clearly explain that confidential patient information would be disclosed to wider NHS organisations in order to facilitate linkage and to make the right of objection more prominent. A revised document should be provided for review.

Specific conditions of support (Provisional)

1. Support extends to England and Wales only.

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

d. 18/CAG/0184 – Long term outcome with congenital heart disease

Context

Purpose of application

This application from Great Ormond Street Hospital for Children NHS Foundation Trust set out the purpose of medical research which aims to undertake follow-up of children who underwent surgery for complex heart defect since 2000 to assess longer term health outcomes in this patient group.

The patient cohort will be identified from the National Congenital Heart Diseases Audit, which is commissioned by the Healthcare Quality Improvement Partnership (HQIP) and carried out as part of the NICOR (National Institute for Cardiovascular Outcomes Research) programme by Barts Health NHS Trust. The NICOR audit programme operates with support under the Regulations via reference 17/CAG/0071 (non-research activity) and 17/CAG/0078 (extended uses of audit data for research purposes). Confidential patient information will be disclosed to NHS Digital to facilitate linkage with ONS mortality information. The applicants will undertake analysis on a pseudonymised dataset.

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

Confidential patient information requested

Cohort

Patients recorded within the National Congenital Heart Diseases Audit between 01 April 2000 and 31 March 2018 as having procedures (both surgery and catheter) for complex heart defects. The audit contains an estimated 120,000 patients.

Confidential patient information will be identified from the National Congenital Heart Diseases Audit held by Barts Health NHS Trust to be released to NHS Digital for linkage. The following items of confidential patient information are required for the purposes stated:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Hospital ID – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Postcode – sample validation and linkage,
- 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 agreed that understanding the longer term outcome for patients who underwent surgery for complex heart defects was in the public interest.

Cohort

The Group noted that the patient cohort for inclusion in the study would be identified from the congenital heart disease audit, which currently held records in relation to 120,000 patients. Members were unclear how many of this overarching sample would be included in the proposed research. It was agreed that clarification would be requested.

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 applicant had stated that consent was not feasible due to the size of the retrospective cohort to be included in the study. The Group commented that the proposed sample size for the study had not been clarified within the application so an informed assessment could not be undertaken on the validity of this rationale at present. It was further commented that a stronger justification could have been made by the applicant that did not only rely on the cohort size. Members suggested that facilitation of a consenting mechanism would require a more significant breach of patient confidence and the implementation of a consent process could also lead to sample bias. It was also noted that the source dataset was collated with support under the Regulations, making consenting for research purposes more difficult.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage undertaken by NHS Digital with wider datasets, which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to facilitate the proposed activity. No queries were raised in this area.

Exit Strategy

Support was requested to facilitate the data linkage process only – the applicant had stated that it was anticipated that the confidential patient information shared to facilitate this process would be deleted by December 2021. 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 Group recognised the activity undertaken in this area with parents and appropriate third sector organisations, which were in support of the project. The importance of feeding back research findings to parents had also been acknowledged within this work. The applicant confirmed that a supplementary grant had been secured to facilitate the production of parent and family information from the study outcomes. Members agreed that the activity in this area was appropriate and proportionate to the proposed activity and raised no issues.

The CAG noted that a proportion of the patient cohort to be included in the study would now be young persons or adults. It was recommended that the applicants consider how this group could be included in the future patient and public involvement activity which is planned in the project, to ensure that the views of the relevant patient cohort are also accounted for. Members agreed that this point did not require any specific action at this stage; however, a condition would be added to the recommendation of support to seek feedback at annual review around any developments which had been made.

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 applicant confirmed that they were working with NICOR to facilitate a project-specific objection mechanism. Supporting information for the website was being devised. The CAG confirmed that sight of this documentation was required prior to any final recommendation of support coming into effect. It was advised that a telephone number, together with email and postal addresses should be provided to facilitate patient dissent. The document should also describe any lead time for raising an objection.

Members also noted that some of the patient cohort to be included in the study would be young persons or adults now, which should be taken into account when drafting the notification text.

The Group recognised the work which had been undertaken by the applicant to establish links with appropriate charities and it was commented that these existing relationships could be built on in order to promote the project more widely. Members agreed that the linked charities should be approached around displaying the information leaflet on their websites in order to widen the communications strategy for the project. Feedback would be 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

1. Clarify the sample size to be included in the project from the overarching audit cohort.
2. Provide a copy of the patient notification text for consideration. This should include telephone, email and postal contacts to facilitate objection, a lead-in time to enable dissent to be raised and also account for the potential for patients within the cohort to now be adults.
3. An approach should be made to the charities with which links were already established to explore the potential of including information around the study on their websites in order to widen the communications strategy for the project. Feedback should be provided around these discussions, together with copies of any text which would be displayed on the websites

Specific conditions of support (Provisional)

1. Consider ways to include young persons and adults who underwent surgery for complex heart defect when they were young within the patient and public involvement and engagement activities for the study. Feedback should be provided at the time of annual review around the progress which has been made here, together with an overview of any activity carried out.
2. Favourable opinion from a Research Ethics Committee (**Confirmed**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed: Barts Health NHS Trust (covering NICOR), and NHS Digital – published satisfactory reviewed grade on v14.1, 2017/18**).

e. 18/CAG/0185 – At-Risk Registers Integrated into primary care to Stop Asthma crises

Context

Purpose of application

This application from the University of East Anglia set out the purpose of medical research which aims to assess whether care provided to patients with asthma, which are at greater risk of hospital admissions and dying from their condition, can be improved via a GP-practice led intervention. The study has recruited 270 GP practices across England, Wales and Scotland in an attempt to identify approximately 10,000 patients who are at-risk of having severe asthma attacks. Half of these practices were randomised to receive a computerised alert message whenever one of the at-risk patients made contact with any member of the practice staff. Practice staff received training in how to manage the alert system, which included making urgent appointments, advising patients to take their medication and follow their written asthma action plans and pharmacists to ensure patients take their medication. The study will follow-up all patients within participating practices with an asthma diagnosis to ensure the intervention is workable for all patients and does not divert resources away from the wider asthma patient population.

This application has been submitted to the CAG to enable follow-up of patients at participating GP practices via administrative datasets held by NHS Digital. The application relates only to the sites in England. Information will be collected on A&E attendance, hospital admissions and deaths due to asthma. Practices will be followed up for a 12 month period. The applicants will also measure asthma control, medications prescribed, attendance for routine appointments and smoking cessation. This information will be used to calculate how much this costs and whether it improves (or interferes with) the care of other patients with asthma in the practices. The study also involves a consented qualitative element which will involve focus groups and interviews for patients and staff, to discuss thoughts about the at-risk registers, the training, and how it worked in practice. This element is out of scope for the CAG application as it will be operated on a consented basis.

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

Confidential patient information requested

Cohort

All patients with an asthma diagnosis across 222 English and 10 Welsh border GP practices recruited to the study. It is estimated that there will be 147,000 patients in total within this sample, of which, 10,000 will be at-risk of severe asthma attacks.

Confidential patient information will be disclosed from participating GP Practices to NHS Digital, via Harvey Walsh, in order to facilitate linkage with administrative datasets. The following items of confidential patient information are requested for the purposes set out:

- NHS Number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Sex – sample validation and linkage.
- Date and cause of death (MM/YY format) – analysis,
- Registered GP practice code – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application described an appropriate medical purpose, which was medical research. Members were assured that any increased knowledge in the management of care for patients with severe asthma was within the public interest due to the potential benefit to a wider patient cohort.

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 were assured by the rationale provided by the applicant around the size of the patient cohort, which made operating the study on a consented basis unfeasible.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage with wider administrative datasets held by NHS Digital, which could not be otherwise achieved. It was recognised that Scottish and Welsh patients were also included in the study; however, an alternative means of follow-up had been agreed for these patients which did not involve processing confidential patient information.

Justification of identifiers

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

Data Flows

Members commented that the data flow chart which had been provided was clear and useful in understanding the transfer of data between the various organisations involved in the study. The Group commented that any transfer of data to NHS Digital would need to be undertaken via a secure network and clarification would be sought from the applicant around this point.

Exit Strategy

Support was requested to support the data linkage process only – the applicant was unable to provide a definitive time period for this process as wider approvals remained pending. However, it was confirmed that following confirmation of successful receipt via NHS Digital, confidential patient information would be immediately destroyed by Harvey Walsh. Members received the clarification and it was noted that an update would be required as part of the standard annual process around the ongoing requirement for 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. Members recognised the considerable work which had been undertaken in this area and it was acknowledged that this had impacted on the study and this would be promoted in the public arena. Further activity was planned as the project progressed. The CAG was assured that the activity in this area was appropriate and proportionate to the proposed activity and no raised no queries 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 applicant confirmed that the fair processing materials provided with the application would be used to fulfil both the requirements under current data protection legislation and requirements for patient notification in relation to the common law duty of confidentiality. Members reviewed the documentation and it was agreed that the document which

was intended to be a poster appeared much too complex and would be more appropriate as a leaflet. It was agreed that a simpler document should be provided in poster format, which could be supplemented by the existing document in leaflet format.

It was noted that current text of the document stated that the project had been reviewed and approved by the Confidentiality Advisory Group, which was not accurate and would require revision. It was further noted that the information around the dissenting mechanism should be made more prominent in the text, with the inclusion of a heading. The Group agreed that a copy of the revised notification materials would be required prior to any final recommendation 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

1. Confirm that the data transfer to NHS Digital would be carried out via secure network.
2. The patient notification documentation for the study should be revised to address the following points:
   a. The document currently labelled as the poster should be utilised as an information leaflet,
   b. The patient's right to dissent should be made more prominent in the text via the inclusion of a heading,
   c. The reference to approval by the CAG should be revised to: The study has been approved by the Health Research Authority, following guidance from the Confidentiality Advisory Group (CAG), an independent body which provides expert advice on the use of confidential patient information',
   d. A simpler document should be drafted as a poster, which provides a high-level description of the study and references the available information leaflet for further information.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital has a published satisfactory reviewed grade on V14.1, 2017/18 and Harvey Walsh Ltd. have submitted a DSPT 2018/19 – NHS Digital confirmed by email 12/11 that standards have been met (equivalent of satisfactory rating on IGTK**).

f. 18/CAG/0186 – Prognostic value of coronary ischaemic burden in aortic stenosis v2

Context

<u>Purpose of application</u>

This application from King´s College Hospital set out the purpose of medical research which aims to assess the importance narrowing in the blood vessels that supply the heart muscle in patients with aortic stenosis (narrowing of the aortic valve) with a new test which uses specialist computer software applied to pictures of the coronary arteries (coronary angiography). It is currently unknown how patients with blood vessel narrowing are affected, particularly in patients who are treated with keyhole surgery for aortic stenosis (TAVI). The study aims to increase understanding of the significance of coronary artery narrowings in patients with aortic stenosis and to provide information on how these patients would be best treated.

The applicants will screen local hospital records for all patients treated with TAVI over the previous eight years in order to identify the cohort eligible for inclusion in the study. The research team are members of

the clinical care team and have legitimate access to patient records; however, mortality checks will be undertaken via linkage with NHS Digital in order to determine which patients are alive in order to contact them to seek consent to participate in the study. Support under the Regulations is sought to support the disclosure of confidential patient information from King's College Hospital to NHS Digital and linkage with mortality information.

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

Confidential patient information requested

Cohort

Patients who underwent keyhole surgery for aortic stenosis (TAVI), between 29 August 2007 and 06 October 2017, at King's College Hospital. It is estimated that 600 patients would be included in the sample.

Confidential patient information will be disclosed by the direct care team at King's College Hospital to NHS Digital in order to linkage with ONS mortality information and HES data. The following items of confidential patient information are cited as necessary for the purposes specified:

- NHS number – sample validation and linkage,
- Hospital ID – sample validation,
- Date and cause of death – sample validation and analysis,
- Postcode – sample validation,

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members were assured that there was public interest in improving the knowledge base around the significance of coronary artery narrowings in patients with aortic stenosis.

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 support under the Regulations was being sought to undertake mortality status checks on the patient cohort, prior to a formal invitation process to participate in the study. Members were assured that it was not feasible to seek consent for this prior data processing which was required to confirm the living patient cohort to be approached for consent.

- Use of anonymised/pseudonymised data

Confidential patient information is required to facilitate the linkage with ONS mortality information which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The application did not clearly specify which items of confidential patient information would be disclosed to NHS Digital in order to facilitate linkage with the ONS dataset. Detail within the application appeared to set out all items of confidential patient information that were required to fulfil the overall study. However, Members stated that, within the scope of the CAG application, confirmation was required around what

would be disclosed to and returned from NHS Digital. Clarification was required in this area prior to any final recommendation of support coming into effect.

Data Flows

The Group noted that correspondence from the REC had stated that the applicants had intended to make contact with patient's GPs; however, this process did not appear to have been described within the application. It was unclear whether, through the proposed data linkage via NHS Digital, the study methodology had evolved and there was now no requirement to follow-up via GPs. Members agreed that clarification would be sought from the applicant to ensure that scope of support required for the proposed activity was clear.

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 applicant had advised that, following receipt of all regulatory approvals, it was anticipated that the data linkage process would take one month to complete, following which disclosed information would be held by the applicant for a further 18 months. The CAG was unclear whether the data linkage process could be achieved the proposed timeframe; however, it was recognised that support when recommended would be in place for 12 months and the applicant would be required to provide an update on progress within the annual review.

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 explained that patients who had undergone the TAVI procedure were surveyed within outpatient appointments to seek views on the study and it was reported that they were supportive of the proposed methodology. The Group recognised that whilst the proposed activity involved a minimal level of intrusion and any patient and public involvement and engagement activity should be proportionate to this. Members were assured that an informal survey with the relevant patient group appeared appropriate in these circumstances; however, it was unclear from the information provided how many patients had been approached about their views. The Group agreed that clarification would be sought from the applicant around the scale of the activity which had been carried out 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. In response to queries, the applicant had confirmed that a poster would be displayed in the outpatient clinic where patients having undergone the TAVI procedure would be reviewed; however, a copy of this document was not provided for review. The Group agreed that sight of this document was required prior to any final recommendation of support coming into effect. Members agreed that the poster should be supplemented by more detailed information on the Trust website. The applicant would be asked to provide a draft of this text for consideration also. The Group advised that a number of contact means should be provided to enable patients to object to their data processing and a lead in time should be detailed to allow a period for meaningful dissent to be raised, prior to linkage via NHS Digital. The applicant would be asked to provide details of how the objection mechanism would be operated.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the requirements of the General Data Protection Regulations (GDPR) implemented through the Data Protection Act 2018. Confirmation is required around the lawful basis which is being relied upon for processing in

relation to Article 6 and Article 9 of the GDPR for the purposes of the application activity. Clarification would be sought from the applicant prior to any final recommendation of support coming into effect.

Other Points

The Group commented that that the proposal had been difficult to consider due to discrepancies between the application form and the protocol. It was noted that there was considerable use of acronyms throughout the documentation, not all of which had been defined within the list of abbreviations included in the protocol. It was recognised that, within the REC review, comments had been made around the use of acronyms in the patient-facing documentation. The CAG agreed that any documentation which had been revised in light of these comments should also be provided for consideration.

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 what items of confidential patient information will be disclosed to NHS Digital to facilitate linkage.
2. Provide an overview of the dataset which would be returned from NHS Digital following linkage.
3. Clarify whether any patient follow-up will be undertaken with the registered GPs.
4. Provide further detail around the patient engagement activity which was undertaken around the study, providing details of when this was carried out and how many patients were approached for their views.
5. Patient notifications and Dissent – further information is required in this area to address the following points:
    a. Provide a copy of the poster which would be displayed in outpatient clinics,
    b. The poster should be supplemented by more detailed information on the Trust website – provide a copy of this text,
    c. Both documents should provide details of how a patient can raise an objection to the use of their data in the study – telephone, email and postal contacts should be provided,
    d. Provide an overview of how the dissenting mechanism would be operated for the study, together with an explanation of the lead in time to enable objection to the raised prior to disclosure to NHS Digital.
6. Confirm what lawful basis which is being relied upon for data processing in the study in relation to Article 6 and Article 9 of the GDPR.
7. Provide copies of any revised documentation which was updated following REC review.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital has a published satisfactory reviewed grade on V14.1, 2017/18**).

5. AMENDMENTS - NON-RESEARCH

a. CAG 8-02 (a-c)/2014 Assuring Transformation Programme

Context

Purpose of application

This suite of three applications from NHS England, on behalf of Clinical Commissioning Groups, reflected the different data flows involved in the initiative known as 'Assuring Transformation', which is the published national data collection monitoring the number of people with learning difficulties and/or autism receiving inpatient care, the quality of the care they receive and progress towards helping people to leave hospital to live in the community. The overarching purpose of these data flows was stated to ensure that a commissioner is always monitoring the overall management of patient care through the activity of 'case management'. Case management was defined in this context to ensure the continuity and quality of care delivered by healthcare providers over the period of the patient's care and to ensure the appropriate support is provided.

i. Sub-Reference: 18/CAG/0191 – Support Duration Extension Amendment

Amendment Request

The amendment requests an extension to support to March 2021 to allow the dual running of the Assuring Transformation programme and collation of data within the Mental Health Services Data Set (MHSDS) until such time as the applicants are confident that the data within the MHSDS of sufficient quality and completeness required by the AT programme.

Confidentiality Advisory Group advice

The CAG considered the history of the application and it was recognised that a duration extension amendment was supported in November 2017. The applicants had sought an extension to March 2020; however, at that time the AT programme was only approved until March 2019. As such, the CAG recommended support in line with the scope of the approved programme until March 2019.

The amendment documentation explained that the documented exit strategy from support under the Regulations, which was collection of the required data via the Mental Health Services Dataset (MHSDS), remained the proposed plan for the activity. The NHS England Learning Disability Programme Board had set specific criteria against which the quality and completeness of data within the MHSDS would be assessed for compliance. It was explained within the amendment submission that analysis against the criteria had been undertaken. A decision was taken at the Board meeting held September 2018 that it was not confident that the required compliance would be achieved by March 2019, which led to the submission of the amendment to extend the duration of support to the AT programme.

Members recognised the ongoing public interest in the AT programme and agreed that the applicant must be assured that the exit strategy would provide complete and robust information before support under the Regulations for the AT programme could be expired. However, the Group was unclear from the detail provided, how the data collected via the MHMDS was not currently achieving the required level of compliance. The CAG agreed that it would be helpful if the report considered by the NHS England Learning Disability Programme Board could be shared, to enable the Group to understand how compliance was measured and the ascertainment comparison between the two datasets. It was agreed that the applicant would be asked to provide this for review by the CAG.

The Group was unclear how the data collection methods differed between the AT programme and the MHMDS. Members agreed that it would be helpful to understand the different processes. It was recognised that the necessary data was available and could be collated, as the AT Programme was currently achieving this. The CAG agreed that further information was required to understand the barriers, perceived or actual, which prevented the MHMDS meeting the required level of compliance. It was further queried what incentive was in place to providers to promote the submission of the required AT information via the MHMDS.

The applicant had provided considerable information within the amendment submission around the work which had been undertaken over the previous 12 months and further planned activity in partnership NHS Digital to improve data collection via the MHMDS. It was noted that the realisation of the exit strategy from support for the AT programme relied heavily on NHS Digital. As such, it would be useful to receive confirmation direct from NHS Digital that it was fully versed in these proposals and endorsed these moving forwards.

The CAG commented that whilst the public interest in the AT programme was evident, ongoing dual processing of data was not sustainable. Members were comfortable that the public interest in the activity outweighed these concerns and support could be recommended for the extension. However, the supplementary information which had been requested by the Group would assist in understanding the current barriers to exiting from support under the Regulations. It was further commented that it would be helpful to understand from the applicant's perspective, whether the exit strategy would be achieved within the scope of the requested extension. The applicant would be asked to provide the requested further information prior to any 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 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

1. Provide details of the compliance criteria which have been established to assess the quality of data collection via the Mental Health Minimum Dataset against the Assuring Transformation Programme.
2. Provide a copy of the most recent compliance report which compared data collection via the Mental Health Minimum Dataset against the Assuring Transformation dataset for consideration.
3. Provide an overview of the data collection methods for the two datasets.
4. Explain any barriers which are known to prevent the MHMDS achieving the same level of data quality as the AT programme. This should also include details of any incentives which are in place to promote the submission of data via MHMDS over the AT programme.
5. Provide confirmation that NHS Digital is aware of and supportive of the proposed activity to improve the data collection via MHMDS.
6. Confirm whether the exit strategy is considered achievable within the scope of current duration extension (i.e. by March 2021).

Specific conditions of support

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS England have a satisfactory reviewed grade on V14.1, 2017/18, email assurance received 27/11/18**).

ii. Sub-Reference: 18/CAG/0190 – Retention Duration Extension Amendment

Amendment Request

The initial application which was considered and supported for the overarching Assuring Transformation programme stated in the response provided to show compliance against principle 5 of the DPA 1998 (Section (r) of the application form):

'Data will be retained in commissioners' registers until 12 months after discharge from in-patient care for these purposes at which point the data will become be deleted, after the CCG confirms that the patient is

not being treated as an in-patient'. The same response was also provided in response at section (aa) of the application form around data retention and destruction.

The application did not distinguish between patient information which included identifiers (confidential patient information) and pseudonymised data. NHS England had interpreted these responses to apply to the direct patient identifiers only and not the wider clinical information which was collected as part of the Assuring Transformation dataset and utilised for analysis in the management and provision of health and social care services.

Following review of the scope of support in place under the Regulations, NHS England submitted this amendment to seek specific support under the Regulations for the ongoing retention and analysis of the pseudonymised data set for five years. It is confirmed that the directly identifiable information will continue to be deleted after 12 months. The information is used by NHS England to effectively monitor commissioner management of patient care and hold commissioners to account.

Confidentiality Advisory Group advice

The CAG was assured that there was a clear public interest in the ongoing retention of the wider clinical data collected within the Assuring Transformation programme, to enable the overarching aims of the programme to be carried out.

The rationale provided by the applicant in support of the amendment stated that, if ongoing retention of the pseudonymised data for the five year period was not supported, it would not be possible to identify patients who were reported to the Assuring Transformation programme more than 12 months late, which would make it difficult if not impossible to understand the rationale for the late report and ensure the individual was receiving quality care. Members were unclear how a patient would be identified within a pseudonymised dataset, unless a linkage key was also being retained. It was also unclear what value the pseudonymised data file would be in this circumstance, if patients could not be identified. It was noted that if a linkage key was being retained; the dataset was not pseudonymised, as there was the ability to re-identify patients.

The Group was content to provide a recommendation of support to the amendment as there were important safeguarding issues and analysis which could not be otherwise addressed without the information. However, it was agreed that clarification was required from the applicant around the format in which the data would be held. Further information was required around the de-identification process which would occur at 12 months post-discharge and whether this meant that direct identifiers would be stripped from the analysis dataset, but retained elsewhere to enable identification of patients who were late reported. If this was the case, Members commented that support could be recommended on the assurance that confidential patient information was stored separately from the clinical data which would facilitate wider analysis. Clarification would be sought from the applicant prior to any 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 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

1. Provide further information around the de-identification process which would occur at 12 months post discharge, clarifying whether a linkage key is retained between confidential patient information and the pseudonymised dataset which would be used for analysis.

Specific conditions of support (Provisional)

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS England have a satisfactory reviewed grade on V14.1, 2017/18, email assurance received 27/11/18**).

b. 17/CAG/0071 (Sub-Reference: 18/CAG/0192) – Barts Health (NICOR) National Cardiac Audit Programme (NCAP) - Amendment for using NCAP (MINAP Domain) data to support Ambulance Clinical Quality Indicator work

Context

Background

The Myocardial Ischaemia National Audit Project (MINAP) is part of the National Cardiac Audit Programme (NCAP) which is hosted at Barts Health NHS Trust. This programme is commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England and the Welsh Government. The purpose of the MINAP audit is to provide NHS services with information about their management of patients with acute coronary syndrome, e.g. heart attack.

NCAP have recently been commissioned to extend the work of the MINAP audit to include a work stream that would include the sharing of data between the audit and NHS Ambulance Trusts.

Amendment Request

This amendment sought to extend support to the flow of data from MINAP to NHS Ambulance Trusts in England in order to enable this linkage. This linkage will enable MINAP to report the following indicators:

- Call to Door times (CtD),
- Patients with initial diagnosis of 'Definite myocardial infarction'.
- Patients who are direct admissions via the emergency services to hospital.
- Call to Door minutes greater than 0 and less than 1000.

This extension to the legal basis would enable:

- NHS Ambulance Trusts to view and export patient information recorded in MINAP database by acute trusts such as time of arrival at hospital, call to door, door to balloon and call to balloon only for patients the acute trust records in MINAP as having been conveyed to hospital by that ambulance Trust.
- NHS Ambulance Trusts to submit information on the pre-hospital care of these patients (already covered in principle by MINAP's existing s251 approval) as well as obtaining permission to potentially include elements/data of pre-hospital care bundle in the ambulance for heart attack patients prior to arrival in hospital such as assessments undertaken by pre-hospital clinicians.

The following are patient identifiable data items that would be shared with NHS Ambulance Trusts:

- NHS number,
- CAD (Computer-Aided Dispatch) number,
- Full name,
- Date of birth,
- Date of death.

Ambulance Trusts will only be able to view and export data in relation to patients that they have transported to hospital. Data from the ambulance Trusts and MINAP will be linked by ambulance job number and/or NHS number.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the proposed amendment had an established medical purpose, through the management of health and social care service. The value of the supplementary data provided by the Ambulance Trusts was recognised and Members were in agreement that there was public interest in this additional data linkage. The Group also recognised that there was established precedent for the inclusion ambulance data within national audit programmes, following the recent recommendation of support which was provided for this linkage in the Sentinel Stroke National Audit Programme.

Support from Healthcare Quality Improvement Partnership (HQIP)

The letter of support for the amendment had been received as part of the submission from HQIP, controller for the audit programme. Ambulance Trusts had provided agreement in principle to the involvement with the audit, which would be managed by the applicant moving forward.

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 reviewed the revised patient notification materials which had been provided as part of the amendment submission. The Group recalled that a previous iteration of this documentation had been considered earlier in the year; however, it was noted that this was prior to the implementation of the General Data Protection Regulations (GDPR) through the Data Protection Act 2018. In light of the transparency guidance in place to ensure compliance with the requirements of the GDPR, the CAG agreed that the text required review to ensure this was accessible to a wide public audience and to make the right to opt-out of data processing more prominent in the text. It was also suggested that alternative communication means could be provided to allow objections to be raised, to supplement the postal contact provided. The CAG agreed that support would be recommended on a conditional basis, with submission of the revised patient notification document required within three months.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Patient notification materials should be revised to address the below points. A revised document should be provided within three months of this outcome:
   a. The documentation should be reviewed to make this more accessible to a wide public audience.
   b. The right to object should be made clearer in the document, with alternative communication methods provided to raise an objection.
2. Support is extended to the data flows between the audit programme and NHS Ambulance Trusts in England.
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Barts Health has a published satisfactory reviewed grade on V14.1, 2017/18. Ambulance Trusts – not requested for each site due to numbers; however, support is recommended on the premise that the applicant will ensure that satisfactory security assurances are in place for each site**).

6. AMENDMENTS – RESEARCH

a. 17/CAG/0078 (Sub-Reference: 18/CAG/0193) – Barts Health (NICOR) National Cardiac Audit Programme (NCAP) – ONS mortality/HES linked data flow for VICORI (Virtual Cardio-oncology research initiative)

Context

Background

The research database was established under the historic reference ECC 4-03(e)/2012 with the aim to develop further the research potential of audit data to understand better the causes of coronary heart disease, timing and evolution of risk, and the interplay between biological, interventional and environmental factors. The research database was transferred to Bart's Health NHS Trust with effect from 01 July 2017, at which point the new application reference 17/CAG/0078 was assigned.

The overall audit application, covered under reference 17/CAG/0071 (historically ECC 1-06 (d)/2011) also transferred to Bart's Health NHS Trust.

Amendment request

This amendment has been submitted to seek support as part of the existing application for the supplementary data flows required for the purposes of the VICORI (Virtual Cardio-oncology research initiative) project. The full title of the VICORI research is '***Cardio-oncology: A high resolution national electronic health record investigation of the interplay between cancer and heart disease'***.

This amendment is to the data flows for National Cardiac Audit Programme (NCAP) to include sharing of wholly pseudonymised NICOR (National Institute for Cardiovascular Outcomes Research) data previously linked by NHS Digital to ONS (Office for National Statistics life status data) and HES (Hospital Episode Statistics) with the National Cancer Registration and Analysis Services (NCRAS) already linked to HES and ONS data at Public Health England for the (Virtual Cardio-Oncology Research Initiative (VICORI) Research Project.

The NICOR audit data is already linked with HES and ONS data as part of these existing approvals; however, the current data sharing agreement with NHS Digital prohibits onward sharing of this information with third parties. An application has been made to NHS Digital for approval for onward sharing of these linked data. As part of this application, NHS Digital has requested that the CAG application be updated to reflect the data flows for this specific project.

This amendment request seeks support for the following data flows:

1. Enable linkage and onward sharing of pseudonymised HES and ONS data already linked to NICOR (HQIP) audit data to PHE. The NICOR audits include:

a. MINAP (Heart attacks)
b. Percutaneous Coronary Intervention (Angioplasty)
c. Adult Cardiac Surgery
d. Cardiac Rhythm Management (Arrhythmia)
e. Congenital Heart Disease
f. Heart Failure
g. Linked HES
h. Linked ONS

2. To link the above to pseudonymised National Cancer Registration and Analysis Service (NCRAS) data already linked to HES and ONS data at Public Health England (PHE) Office for Data Release (ODR) - according to the memorandum of understanding between NHS Digital and PHE. The NCRAS data includes:

a. Site specific cancer
b. Audits
c. Existing links:
    - Systemic Anti-Cancer Therapy Dataset,
    - the National Radiotherapy Dataset
    - Linked HES
    - Linked ONS

Confidentiality Advisory Group advice

Public interest

The CAG noted that the amendment defined an appropriate medical purpose, which was medical research via the VICORI project. It was recognised that the purpose of the amendment was to seek support for the onward disclosure of pseudonymised linked NICOR, NCRAS, HES and ONS data for the specific purposes of the VICORI project. It was recognised that the NICOR dataset was already linked with HES and ONS data and support was in place under this existing approval for the use of this linked audit data for secondary research purposes. However, the previous data sharing agreement which was in place with NHS Digital prohibited onward sharing of HES and ONS data. An application had been made to NHS Digital to update the data sharing agreement to enable onward disclosure of pseudonymised data and it had been requested that the CAG application be updated to reflect this also.

The Group recognised that that the VICORI was clearly in the public interest. It was noted that the programme was funded by appropriate charities and had established sound patient and public involvement and engagement activities. Members understood the rationale behind the amendment and were content to provide a recommendation of support on this basis.

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 reviewed the revised patient notification materials which had been provided as part of the amendment submission. The Group recalled that a previous iteration of this documentation had been considered earlier in the year; however, it was noted that this was prior to the implementation of the General Data Protection Regulations through the Data Protection Act 2018. In light of the transparency guidance in place to ensure compliance with the requirements of the GDPR, the CAG agreed that the text required review to ensure this was accessible to a wide public audience and to make the right to opt-out of data processing more prominent in the text. It was also suggested that alternative communication means could be provided to allow objections to be raised, to supplement the postal contact provided. The CAG agreed that support would be recommended on a conditional basis, with submission of the revised patient notification document required within three months.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Patient notification materials should revised to address the below points. A revised document should be provided within three months of this outcome:
   a. The documentation should be reviewed to make this more accessible to a wide public audience.
   b. The right to object should be made clearer in the document, with alternative communication methods provided to raise an objection.
2. Favourable opinion from a Research Ethics Committee (**Confirmed**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Barts Health has a published satisfactory reviewed grade on V14.1, 2017/18**).

7. MINUTES OF THE MEETING HELD ON 18 OCTOBER 2018

The minutes were received and accepted as a accurate record of proceedings.

8. ANY OTHER BUSINESS

Members discussed potential educational items for consideration at a later date. Suggestions were recorded by the Confidentiality Advice Team to be raised with the Chair Team.

The Confidentiality Advice Team reminded Members to submit any expense claims in a timely fashion as the financial year approached.

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