Health Research Authority

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

May 2018

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1. NEW AMENDMENTS

Reviewers:

Name	Capacity
Ms Clare Sanderson	Alternate Vice-Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Tracking the Impact of Gestational Age on health, educational and economic outcomes: a longitudinal Record linkage study (TIGAR)**

CAG reference: **15/CAG/0196**

Context

Purpose of Application

This application from University of Oxford set out the purpose of the overall aim of the study to investigate the effect of gestational age at birth on health, educational and economic outcomes up to age 11 years.

TIGAR will use information about all children born in England during 2005/2006 (about one million). Information on the children will be obtained from: birth records; records of hospital admissions or outpatient visits up to age 10 years and primary school records (e.g. SATs results, special educational needs). The information from these sources will be linked together by independent organisations, which will make the data completely anonymous before sending it to the TIGAR team for analysis.

Support is requested to allow the disclosure of confidential patient information from:

- The HSCIC to the Office for National Statistics (ONS)
- The ONS to the Education Data Division
- The TIGAR team to access patient confidential information within the ONS VML – this is for validation purposes

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

Confidential patient information requested

Access was requested to child name, sex, date of birth and most recent postcode for the linking process.

A later amendment was requested (and supported) to include date of death for analysis.

Amendment Request

The application sought an extension to the duration of support until 30 June 2020.

The applicants further explained that, due to delays in the release of pseudonymised data from ONS to the University of Oxford, the analysis of the pseudonymised data would begin at the ONS in London, pending the approval of data release. The applicants explained that this decision had been taken as the project was behind schedule.

Some additional administrative changes were notified which included a change to project staffing and replacement of references to 'ONS Virtual Microprocessor Laboratory (VML)' with 'ONS Secure Research Service (SRS)', due to recent name change.

Confidentiality Advisory Group Advice

The amendment requested was considered by the Alternate Vice-Chair, who reviewed the documentation and was content to provide a recommendation of support to the amendment.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Alternate Vice-Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission **(Confirmed - NPEU, University of Oxford – v14 .1, 14/05/2018).**
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed 03/05/18).**

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice-Chair
Dr Rachel Knowles	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Andrew Melville	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **National Asthma and Chronic Obstructive Pulmonary Disease (COPD) Audit Programme**

CAG reference: **CAG 8-06(b)/2013**

Context

Purpose of Application

This audit application from the Royal College of Physicians of London (RCP) set out the purpose of collecting primary and secondary care clinical data to inform the national audit programme.

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

Confidential Patient Information Requested

Access was requested to NHS number, postcode, date of birth, date of death (if died as an inpatient) and gender.

Background to the Amendment Request

Support under the application currently extended to the National Chronic Obstructive Pulmonary Disease (COPD) Audit programme. This programme was recently retendered by Health Quality Improvement Partnership; however, the scope of the audit programme under the recent tender proposal was extended in order to merge the adult asthma audit into the COPD audit programme. The Royal College of Physicians, who previously ran the National COPD Audit, was successfully awarded the contract for the new merged Asthma and COPD audit programme.

Amendment Request

This amendment sought support to extend the scope of support to include the collection of data to facilitate the adult asthma audit programme. The name of the audit programme had been updated and was now the National Asthma and COPD Audit. It was confirmed that the inclusion of the asthma data collection within the existing application would not require any additional items of confidential patient information. Support was also requested to extend to the collection of secondary care information for both asthma and COPD patients.

Confidentiality Advisory Group Advice

The amendment request was shared with a Sub-Committee of the Confidentiality Advisory Group for consideration. The extension to the audit programme had been commissioned by HQIP and advertised as part of a retendering exercise, which was awarded to the applicants who had previously ran the COPD audit programme.

Members acknowledged that the amendment proposed a significant change through the inclusion of an additional, but closely related diagnosis to the audit programme. It was recognised that the data collection methodology would remain the same and there was no requirement for additional items of confidential patient information to be collected.

The Group was assured that it was not possible to seek consent from patients within the adult asthma cohort, due to the size of the cohort and the inappropriateness of such a discussion when a patient had been admitted to hospital was also accepted.

The applicants had provided patient information materials to support the adult asthma audit, which included a poster and information leaflet. Members agreed that the documentation provided a clear overview of the audit and an opt-out mechanism. No further issues were raised in this area.

The CAG was assured that there was an appropriate medical purpose, through the management of health and care services, and ongoing public interest in these activities continuing and was content to provide a recommendation of support to the amendment.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Sub-Committee agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – Imperial College London, Crown Informatics Ltd. and Royal College of Physicians of London – Version 14.1, 2017/18 confirmed as satisfactory in email from NHS Digital received 17/05/2018**).

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice-Chair
Dr William Bernal	CAG Member
Dr Lorna Fraser	CAG Member
Dr Jennifer Kurinczuk	CAG Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **London Borough of Tower Hamlets Whole Systems Data Integration Project**

CAG reference: **17/CAG/0100**

Context

Purpose of Application

As one of the most deprived boroughs in England, Tower Hamlets is attempting to efficiently improve overall health outcomes while addressing health inequalities. The intention of this project is to underpin this strategy with evidence identifying the key drivers of health inequalities with respect to health status and service usage. Tower Hamlets already benefits from an integrated care dataset that links data across different settings of care: primary care, community health, mental health, secondary care and adult social care. This was established as part of the Waltham Forest, East London collaborative (WELC) Integrated Care Pioneer Programme in order to map a proposed capitated budgets model based on 14/15 data. The applicants propose to build on this good practice by linking these datasets as well as children's services data and wider determinants data, which are held and owned by the local authority.

To establish a truly integrated and pseudonymised health and social care (H&SC) dataset for the local population which combines information from the London Borough of Tower Hamlets (LBTH), Local Authorities and wider health care sectors so as to:

- Define, inform and implement capitated budget for the Tower Hamlet population.

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

Confidential Patient Information Requested

Data from the London Borough of Tower Hamlets (LBTH), local authorities, and wider health sectors in relation to the resident population of the London Borough of Tower Hamlets (296,000):

- NHS Number,
- Full Name,
- Full Address (including postcode),
- Date of Birth,
- Date of Death,

- Gender,
- GP Code; & Unique Property Reference Number (UPRN) [a unique alphanumeric identifier for every spatial address in Great Britain].

Amendment Request

This amendment request was submitted to seek approval to extend the duration of support under the Regulations to 31 March 2019.

A clarification point was also included within the amendment documentation to confirm that the Clinical Effectiveness Group at Queen Mary University of London (CEG QMUL) is acting as the data processor for the project.

The applicants also submitted an interim six month progress report for consideration by the CAG, in line with the conditions which were attached to the recommendation of support. This was considered by the Sub-Committee in conjunction with the amendment request.

Confidentiality Advisory Group Advice

The amendment request and interim progress report was shared with a Sub-Committee of the main CAG for consideration.

The applicants had explained that delays had been experienced in receiving the required approvals from the data controllers providing data for the project. It was confirmed that approvals were now in place; however, the applicants required additional support under the Regulations to enable the linkage and depersonalisation of the data to be carried out. Members acknowledged that this was a large and complex study and were sympathetic to the delays which had been experienced. The Sub-Committee was content to recommend an extension to the duration of support provided under the Regulations to 31 March 2019, to enable completion of the project.

The clarification of the data processor for the project was acknowledged with no action required by Members.

The Sub-Committee considered the interim six month progress report and commended the level of work which had been achieved by the applicants within this period. Whilst Members were reasonably assured by the content of the report, further work was required in some areas to be reported back at the time of first annual review.

The Group agreed that the project Steering Group should include more than one lay representative. It was recognised that this was a large project within which the views of the local population were important. The applicants would be required to improve the lay representation on the Steering Group and report back on this at the time of first annual review.

Members also agreed that further work was required in relation to the opt-out mechanism for the project. The difficulties in achieving an opt-out mechanism for the project, which involved a number of large and sensitive datasets was recognised; however, the Group stated this was why the establishment of a meaningful objection was such a key requirement for the project. In particular, it was noted that information supplied from the Local Authority was likely to be regarded as highly sensitive by local residents.

The Group agreed that the applicants should undertake further to improve to the opt-out mechanism and ensure that a project-specific objection was available and communicated in a manner which was accessible to the wide audience that could be included in the project.

Concerns were expressed in the report that opting-out was not well understood by residents and staff. The Sub-Committee recommended that further patient and public involvement and engagement and communication work was required to resolve this.

The applicants would be required to provide feedback on the further progress which has been achieved in these areas at the time of annual review.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Sub-Committee agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific Conditions of Support

1. Support is extended to 31 March 2019.
2. Further work should be undertaken to improve the lay representation on the project Steering Group. Feedback on the progress achieved is required at annual review.
3. Further work should be undertaken to improve the project-specific objection mechanism. This should be informed by wider communication plans and additional patient and public involvement and engagement. Feedback on the work undertaken is required at annual review, together with an overview of the improved objection mechanism and how this was operated.
4. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Version 14.1, 2017/18, NHS Digital email confirmed 21 May 2018).**

2. Applications

Reviewers:

Name	Capacity
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **REACH Pregnancy Circles:An individual-level randomised controlled trial of group antenatal care**
CAG reference: **17/CAG/0186**
IRAS project ID: **228894**
REC reference: **17/LO/1596**

Context

Purpose of Application

This research study from the University of East London set out the purpose of completing a randomised controlled trial (RCT) of a model of group antenatal care called Pregnancy Circles offered to women living in deprived and ethnically mixed parts of London, Essex and Bedfordshire. The trial aims to test the effectiveness of the group-based care. This RCT follows a pilot trial which tested feasibility of, and best methods for, the trial.

A Pregnancy Circle involves about 12 pregnant women, who live close to each other and are due to give birth around the same time, having their antenatal care together in a community setting. The groups are facilitated by 2 midwives who combine clinical care with antenatal education and peer support. Care is organized in this way for the groups of women throughout their pregnancy and replaces standard antenatal care. There is good evidence from other settings that group antenatal care has a positive impact on women's experiences of antenatal services and may lead to better health outcomes. This study would test the effectiveness of this model of care by primarily looking at any increases in rates of vaginal birth for these groups.

Section 251 support was sought to enable researchers to assist clinical care staff with recruitment. The research team would identify suitable participants from referral records, and provide information by post before consent was requested at direct care appointments.

A recommendation for class 3 and 6 was requested to select and contact participants to seek their consent, and to allow access to an authorised user for the above purpose.

Confidential Patient Information Requested

Access was requested to data from the referral record of participating maternity services, in relation to women who are currently pregnant and registered for antenatal care with one of the included maternity services, who also live within the working area covered by the Pregnancy Circle trained midwives, have an estimated delivery date that fits with a proposed pregnancy circle, and are over 16:

- Name
- Address
- NHS Number
- Estimated date of delivery

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 (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 27 April 2018)**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmation is not required for each individual site, however support is recommended on the understanding that the applicant will ensure that the appropriate security assurances are in place at each site**).

Reviewers:

Name	Capacity
Dr Tony Calland MBE	Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Transient patella dislocation and mode of early mobilisation**
CAG reference: **18/CAG/0004**
IRAS project ID: **234991**
REC reference: **17/EM/0445**

Context

Purpose of Application

This application from the Heart of England NHS Foundation Trust sets out the purpose of medical research which aims to find out if there is an increase in the likelihood of knee cap dislocation among people that were bottom shufflers and/or straight to walkers compared to those that crawled. Walking also changes the dynamics operating between the knee cap and the trochlea. A secondary aim will be to find out if there is any relationship between age of onset of independent walking and knee cap dislocation in later life.

Support is requested to allow the main applicant access to computerised medical records of MRI scans on the radiology reporting system in order to identify an eligible patient cohort to be invited to participate in the study. Confidential patient information will used to facilitate the invitation and consent process.

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

Confidential Patient Information Requested

Cohort

- Patient – aged between 10 and 35 years, with record of a knee cap dislocation within the last three years.
- Control – aged between 18 and 35 years, who have undergone an MRI scan of the knee in the last three years but without evidence of malfunction between the patella and femur articulation (patellofemoral dysfunction) or rupture of the anterior cruciate ligament of the knee, which can be related to patellofemoral dysfunction.
- 200 patients in total will be invited (100 per cohort).

Eligible patients will be identified using a key word/phrase search of the radiology reporting systems. The following items of confidential patient information will be recorded for eligible patients for the purposes outlined:

- Name – to send out invitation/questionnaires,
- Full address and postcode – to send out invitation/questionnaires,
- Date of birth – sample validation and analysis,
- Sex – recorded for analysis.

Confidentiality Advisory Group Advice

The applicant provided a written response to the request for further information detailed in the previously issued provisionally supported outcome. This was considered by the Chair in correspondence.

1. **Confirm that patient medical records will be checked for evidence of previously recorded dissent against the use of data for research purposes, prior to participant invitation materials being issued.**

The applicant confirmed that records would be checked for evidence of historic dissent.

The response was received and no further issues were raised.

2. **Patient and Public Involvement and Engagement Activity – further information is required to address the following points:**
   a. **Provide an overview of the composition and membership of the Clinical Research Ambassador Group,**

It was clarified that the Ambassador Group was made up of both patients and hospital staff.

The response was received and no further issues were raised in this area.

   b. **Provide feedback from the engagement activity which was undertaken and any feedback which was provided around the project and proposed use of confidential patient information without consent. Should the feedback be negative, the CAG will take this into account when considering whether support can be recommended for the activity.**

The applicants confirmed that the Clinical Research Ambassador Group voted unanimously in favour of allowing access to confidential patient information without prior consent for the purpose of this study.

The response was received and no further issues were raised in this area.

Recommendation:

The below additional points have been included as a recommendation only and are not a requirement of the request for further information.

1. **It was recommended that participant information materials for the project are revised to address the following points:**
   a. **The documents should include a title of 'Participant Information Sheet' to highlight that this is not a communication about direct care,**
   b. **A paragraph should be included to explain how the patients were identified to be approached for the research study,**
   c. **The document should explain that by completing and returning the questionnaire, this confirms consent to participate in the study.**

The applicant provided revised documentation within which the recommendations had been actioned.

The documentation was received and no further issues were raised.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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 (Final)

1. Favourable opinion from a Research Ethics Committee. (**Confirmed – 02 January 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Confirmed – Heart of England NHS Foundation Trust, Version 14.1, 2017/18, reviewed satisfactory – email confirmation received 30/05/2018**).

Reviewers:

Name	Capacity
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Improving Prediction of Outcome in Out of Hospital Cardiac Arrest Patients - The King's Out of Hospital Cardiac Arrest Registry (KOCAR)**
CAG reference: **18/CAG/0025**
IRAS project ID: **233062**

Context

Purpose of Application

This application from King's College Hospital NHS Foundation Trust (KCH) sets out the purpose of medical research with a focus on the outcome of patients that suffer out of hospital cardiac arrest (OOHCA). The data will be used to validate a risk stratification tool to support clinical decision making upon admission. Information on patients suffering from OOHCA and subsequently brought to KCH will be collected from the London Ambulance Service (LAS). Information will be requested from NHS Digital on the mortality status of those patients. Those patients that are still living will be contacted by telephone for a follow up interview to identify the outcome of the OOHCA.

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 patients over the age of 18yrs admitted to KCH via London Ambulance Service having suffered an Out of Hospital Cardiac Arrest between 1st May 2012 and 31st December 2017.

Sample size: 400 patients approximately 150 survivors for telephone interview.

- Data released by LAS: Computer Aided Dispatch Number (CAD), date of reaching admitting hospital – linkage. Data obtained under a data sharing agreement,
- Data identified from patient records at KCH: Unique KCH hospital number, NHS number, Occupation, GP and post-code – to facilitate linkage with ONS mortality information at NHS Digital and patient contact.

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 (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 23 April 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital confirmed a satisfactory**

reviewed grade for King's College Hospital NHS Foundation Trust V14.1, 2017/18 and NHS Digital V14.1, 2017/18).

Reviewers:

Name	Capacity
Dr Patrick Coyle	Chair
Dr Lorna Fraser	CAG Member
Dr Rachel Knowles	CAG Member
Ms Gillian Wells	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Mixed methods evaluation of the Getting it Right First Time programme: improvements to NHS orthopaedic care in England**
CAG reference: **18/CAG/0028**
IRAS project ID: **210181**
REC reference: **16/NW/0654**

Context

Purpose of Application

This application from University College London set out the purpose of medical research which aims to evaluate the planned changes to orthopaedics, as part of the 'Getting it Right First Time' Project (GIRFT), to identify lessons to inform future efforts to improve the organisation and delivery of services. The applicants will study documents relating to the changes and interview a wide range of stakeholders (hospital staff, commissioners, and national project team) about how the changes were implemented and what impact they have had. The applicants will analyse performance and cost data before, during and after the changes to assess whether the GIRFT programme has a) reduced variations in both the cost of care and the way it is delivered and b) improved patient outcome measures. We will also conduct focus groups with patients and members of the public to explore their perceptions of the planned improvements to care.

The Getting it Right First Time project (GIRFT) aims to deliver improvements in quality and reductions in the cost of NHS orthopaedic care across England. It involves three core strategies: (1) feedback of performance data to hospitals; (2) tailored written feedback to underperforming hospitals; and (3) changes to the way hospitals are paid, to encourage improvement. The GIRFT approach will in due course be rolled out across nine other NHS surgical specialities.

The application describes a number of activities; however, only studies two and three require CAG consideration. These sub-studies will undertake analysis on dataset of linked information which will be created from the National Joint Registry together with HES and PROMS data provided by NHS Digital. The applicants will only receive a pseudonymised data set for analysis; however, support under the Regulations is required to facilitate the linkage between the datasets.

The applicants state that evaluation will enable them to understand better what works, at what cost, but also to study how changes of this kind are implemented and sustained. Feedback will be provided to change leaders and decision-makers, locally and nationally, as well as identifying lessons to inform future efforts to improve care. Lay versions of the study reports will be produced for patients and the public, as well as management briefings for NHS policy makers, managers and clinical leaders.

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

Confidential Patient Information Requested

Cohort

- The patient cohort will include all elective primary joint replacement procedures carried out in NHS Trusts in England for the period April 2009 to March 2018.
- It is estimated that there will be approximately 1 million patients within this cohort.

Confidential patient information will be transferred from the National Joint Registry to NHS Digital to facilitate data linkage.

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

- NHS number – linkage and analysis,
- Date of birth – linkage,
- Sex – linkage,
- Postcode – linkage and analysis (Deprivation scoring),
- Study ID – linkage and analysis,
- Ethnicity – from NHS Digital for analysis.

Confidentiality Advisory Group Advice

A Sub-Committee of the main CAG considered the applicant's written response to the request for further information provided below in correspondence.

1. **Contact should be made with the National Joint Registry to explore the potential for the pseudonymised dataset required for analysis to be provided direct from the database they currently hold, as a practicable alternative to seeking support under the Regulations. The outcome of these discussions should be provided for consideration. If this option is not feasible, provide clarification as to why this is not possible.**

The applicants explained that they had made contact with the National Joint Registry, (and have also checked back with NHS Digital), to explore the potential for the pseudonymised dataset required for analysis to be provided direct from the NJR database, as a practicable alternative to seeking support under the Regulations. As NHS Digital will undertake linkage in this case, it is not feasible for the NJR to send us the pseudonymised dataset directly.

The Sub-Committee received the response and no further issues were raised in this area.

2. **Confirm the start and end date for the patient cohort to be included within the project.**

It was confirmed that the start date for index cases was 01/04/2009 and the end date for index cases: 31/03/2018 (following a request for a data refresh in 2019).

The clarification was received and no further issues were raised.

3. **Clarify the duration of support which is required under the Regulations to support the processing of confidential patient information without consent.**

The applicants explained that support was required until approximately March 2019; as this would be when the refreshed dataset would be due to arrive at UCL to be checked by the research team. The applicants noted that this date was subject to receipt of the dataset and checking accuracy.

The Sub-Committee received the response and it was noted that, should support be required to extend after March 2019, an amendment would be required for consideration in sufficient time ahead of this existing support expiring.

4. **Confirm whether it is intended that NHS Digital will retain a link file for the duration of the project. If so, provide rationale to support why this is required.**

The applicants confirmed that NHS Digital was not intended to retain a link file for the duration of the project and had confirmed they would only need the linkage variables to be resent to them prior to the request for data refresh.

The Sub-Committee received the response and no further issues were raised in this area.

5. **Patient and Public Involvement and Engagement – further work is required in this area to explore the acceptability of using confidential patient information without consent, as described for this component of the programme. Feedback from the engagement activity should be provided. It was noted that if the feedback given was negative, the CAG would take this into account when considering if support could be recommended.**

The applicants explained that, in order to explore the acceptability of using confidential patient information without consent, they had undertaken an engagement activity, which involved the patient representative on the study steering committee and members of the NIHR CLAHRC North Thames patient and public involvement group. The group was provided a lay summary of the study were asked to complete a feedback form about the planned use of patient data in the study. The applicants provided a copy of the lay summary, feedback form and collated feedback for review by the Sub-Committee.

Members considered the information and whilst the feedback showed that those who had been engaged were supportive of the proposal proceeding, it was commented that the information which was included within the lay summary was quite complex. No further action was required in this area.

6. **Patient Notifications and Dissent – further work is required in this area to address the following points:**
    a. **A patient-focussed communications strategy should be developed which included wider methods to support the web-based information,**
    b. **Notifications should include a patient opt-out mechanism,**
    c. **Copies of any documentation should be submitted for consideration,**
    d. **An overview of how the patient objection mechanism would be operated should be provided.**

The applicants submitted the patient-focussed communications strategy, detailing the patient opt-out mechanism for consideration by the CAG. It was confirmed that this information had been included on the existing study websites. The applicants confirmed that they had also set up a dedicated e-mail address for patients to use.

The Sub-Committee received the response and it was commented that some of the language used within the notification text may be complex for some readers. It was agreed that the applicants should consider ways in which the text could be simplified to make this more accessible to all readers.

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 (Final)

1. Work should be undertaken to review the content of the patient notification materials in order to simplify the content in order to make this accessible to a wider audience. A report back on work undertaken should be provided at first annual review, together with a copy of the revised text for consideration.
2. Favourable opinion from a Research Ethics Committee. (**Confirmed – ethical opinion has been in place for the overall study since 26/08/2016).**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - University College London, School of Life and Medical Sciences show a satisfactory reviewed grade on Version 14.1, 2017/18 and NHS Digital).**

Reviewers:

Name	Capacity
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **REACH Pregnancy Circles:An individual-level randomised controlled trial of group antenatal care**
CAG reference: **17/CAG/0186**
IRAS project ID: **228894**
REC reference: **17/LO/1596**

Context

Purpose of Application

This research study from the University of East London set out the purpose of completing a randomised controlled trial (RCT) of a model of group antenatal care called Pregnancy Circles offered to women living in deprived and ethnically mixed parts of London, Essex and Bedfordshire. The trial aims to test the effectiveness of the group-based care. This RCT follows a pilot trial which tested feasibility of, and best methods for, the trial.

A Pregnancy Circle involves about 12 pregnant women, who live close to each other and are due to give birth around the same time, having their antenatal care together in a community setting. The groups are facilitated by 2 midwives who combine clinical care with antenatal education and peer support. Care is organized in this way for the groups of women throughout their pregnancy and replaces standard antenatal care. There is good evidence from other settings that group antenatal care has a positive impact on women's experiences of antenatal services and may lead to better health outcomes. This study would test the effectiveness of this model of care by primarily looking at any increases in rates of vaginal birth for these groups.

Section 251 support was sought to enable researchers to assist clinical care staff with recruitment. The research team would identify suitable participants from referral records, and provide information by post before consent was requested at direct care appointments.

A recommendation for class 3 and 6 was requested to select and contact participants to seek their consent, and to allow access to an authorised user for the above purpose

Confidential Patient Information Requested

Access was requested to data from the referral record of participating maternity services, in relation to women who are currently pregnant and registered for antenatal care with one of the included maternity services, who also live within the working area covered by the Pregnancy Circle trained midwives, have an estimated delivery date that fits with a proposed pregnancy circle, and are over 16:

- Name
- Address
- NHS Number
- Estimated date of delivery

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 (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 27 April 2018)**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmation is not required for each individual site, however support is recommended on the understanding that the applicant will ensure that the appropriate security assurances are in place at each site. Please see the** information governance toolkit **section of the CAG website for further information**).

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **A Prospective Study of Acute Severe Poisonings In Children**
CAG reference: **18/CAG/0006**
IRAS project ID: **191072**
REC reference: **17/EM/0464**

Context

Purpose of Application

This application from Derby Hospitals NHS Foundation Trust sets out the purpose of medical research which will determine the incidence and identify the circumstances surrounding severe accidental poisoning in children under 15 years in the UK and Republic of Ireland resulting in death, or signs and symptoms of poisoning defined as needing significant monitoring or support. This is a prospective, national, surveillance cohort study, conducted in secondary care in collaboration with the British Paediatric Surveillance Unit (BPSU). Paediatricians within UK and Republic of Ireland will report cases of severe poisoning through the BPSU 'orange card' system over a period of 13 months as part of this study. The BPSU methodology is supported in principle by the CAG.

Accidental poisoning is an avoidable problem and remains an important public health issue. It is well recognised that blanket approaches to public health campaigns are often ineffective. By identifying specific trends in severe poisonings, in particular including specific substances that frequently cause significant harm, it is hoped that these can be subsequently be targeted.

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

Confidential Patient Information Requested

Cohort

All children in England and Wales aged 15 years and under with a diagnosis of acute unintentional or accidental poisoning over a 13 month period (proposed start March/April 2018).

It is estimated that the sample will be approximately 125 children.

The following items of confidential patient information will be disclosed by treating clinicians at individuals Trusts, for the purposes as set out below:

- NHS Number – sample validation and removal of duplicate entries,
- Hospital Number – sample validation and removal of duplicate entries,
- Date of birth – sample validation and removal of duplicate entries and analysis
- Date of death – analysis,
- Gender – analysis,
- Ethnicity – analysis.

All identifiers, with the exception of gender and ethnicity, will be destroyed at the end of the data collection period, when the sample has been validated and duplicate entries removed. Date of birth and death will be used to calculate age at incidence and death, before being destroyed.

Confidentiality Advisory Group Advice

The Vice Chair considered the applicant's written response to the below request for further information, as requested as part of the provisionally supported outcome, in correspondence.

1. **Submit a revised patient information leaflet to address the following point:**
   a. **The paragraph around the option to dissent ('The NHS use medical records…') should be revised to make the right of objection clearer to patients.**

The applicants provided a revised information sheet as requested.

The document was received and no further issues were raised in this area.

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 (Final)

1. Support extends to England and Wales only.
2. Favourable opinion from a Research Ethics Committee. (**Confirmed – 30 January 2018**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Confirmed – Derby Hospitals NHS Foundation Trust, V14.1, 2017/18, satisfactory – by email 14 May 2018**).

Reviewers:

Name	Capacity
Dr Tony Calland MBE	Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Sight-threatening chemical injury study in association with the British Ophthalmological Surveillance Unit**
CAG reference: **18/CAG/0008**
IRAS project ID: **233478**
REC reference: **18/SC/0007**

Context

Purpose of Application

This application from the Buckinghamshire Healthcare NHS Trust set out the purpose of medical research involving a survey of visual compromise resulting from chemical injury, using prospective case ascertainment through the British Ophthalmological Surveillance Unit (BOSU) monthly reporting card scheme. This is an active surveillance system involving all UK consultant ophthalmologists.

The primary aim of this study is to ascertain the incidence of sight-threatening ocular chemical injury in the UK. This is to include demographic details of patients and details of causative chemical and mechanism of injury. The secondary aims of this study are to assess the best corrected visual acuity at presentation and 6 months, and the surgical interventions required.

This is an epidemiological study using only information available from the patient case notes. Ophthalmologists will indicate that they have seen a new case through the BOSU. The BOSU collects no patient identifying information but will notify the study team of all new cases, who will contact the reporting ophthalmologist directly for completion of a questionnaire.

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

Confidential Patient Information Requested

Cohort

All patients (aged up to 150 years) within England and Wales, with a diagnosis of sight-threatening chemical injuries. It is estimated that there will be approximately 100 reported incidences within the 12 month study period.

The following items of confidential patient information will be provided by the treating clinicians at individual Trusts to the applicants for the purposes as set out below:

- Hospital Number – sample validation to remove duplicate entries,
- Date of birth – MM/YY format only for sample validation to remove duplicates and analysis – calculated to age at incident,
- Postcode – district level – geographical analysis,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

The Chair considered the applicant's written response to the below request for further information in correspondence.

1. Provide copies of the patient information materials for the project for consideration.

The applicant supplied copies of the patient information leaflet, which supported the project. It was also confirmed that the information would be displayed on the Royal College of Ophthalmologists' website.

The Chair received the response and document and no further issues were raised.

2. Provide further information around patient and public involvement and engagement plans following correspondence with BOSU, for consideration by the CAG.

The applicant explained that BOSU work with the Lay Advisory Group which is established at the Royal College of Ophthalmologists, so there is patient/public involvement in all BOSU studies through this Group.

The Chair received the response and no further issues were raised.

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 (Final)

1. Support extends information generated in England and Wales only.
2. Favourable opinion from a Research Ethics Committee. (**Confirmed – 22 March 2018**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission or future replacement. (Confirmation received from NHS Digital (**Received 02/05/2018**).
4. Maintenance of satisfactory security arrangements for the duration of the support.

Reviewers:

Name	Capacity
Dr Tony Calland MBE	Chair
Ms Sophie Brannan	CAG Lay Member
Mr Anthony Kane	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from the Northumbria Healthcare NHS Foundation Trust sets out the purpose the development and establishment of a national registry for Bone and Joint Infections in the United Kingdom, which is intended to be used for audit and service evaluation. Bone and joint infections are a significant cause of morbidity and mortality that affect patients of all ages. Understanding current standards for care and effectiveness of interventions and care pathways is a major challenge for surgeons, physicians, microbiologists and patients. This project seeks to capture data about affected patients and the care they receive for these debilitating and often fatal conditions. Linkage with the HES dataset is proposed via NHS Digital; however, this element is outside of the CAG's remit as patients will be asked to consent to this element. This will enable robust understanding of the current care pathways, insight into which treatments are most effective and comparisons between different units of the patient outcomes they achieve.

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

Confidential Patient Information Requested

Cohort

All patients aged over 18 who suffer from infection involving native bones and/or joints or related to medical devices in bones or joints within England and Wales.

Data will be provided from individual treating Trusts by entry into a web-based registry.

The following items of confidential patient information will be requested, together with a wider clinical dataset, for the purposes as detailed:

- Date of Birth – validation and linkage,
- NHS number – validation and linkage,
- Age – analysis,
- Sex – analysis,
- Date of death – analysis,
- Ethnicity – analysis,
- Hospital Unit Identifier – validation and analysis,
- Date of admission – validation and analysis,
- Date and time of discharge – validation and analysis.

Confidentiality Advisory Group Advice

The application was a resubmission of the project previously considered under reference 17/CAG/0140, which was initially considered at the CAG meeting held on 28 September 2017. The CAG deferred recommendation on the proposal at this meeting, pending further information from the applicants. The applicants provided a written response to the request for further information, which was reviewed by a Sub-Committee of the CAG in correspondence.

1. **Further information is required around the data collection methodology – a clearer articulation of the proposed methodology should be provided, taking the following points into account:**
   a. **Clarify how case ascertainment will be maximised, also addressing how it will be known how accurate the captured sample if against the true patient cohort,**

The applicants explained that there were two aspects to case ascertainment. The first was to detect that all the relevant cases are included on the registry. The second is that those who are registered have comprehensive record of all subsequent care episodes. The following points were made to emphasise how case ascertainment would be maximised:

1. There is a national push to refine bone and joint infection services, which is being directed by the 'Getting It Right First Time' programme. AS such, each Trust has a clear incentive to register all possible cases of bone and joint infection in order to justify their service and its subsequent funding.
2. Each Trust will be asked to review cases submitted to the registry on an annual basis via a PAS export that will identify any further clinical activity on the BAJIR registered patients. Where PAS suggests further intervention, the local registry representative will be asked to clarify all further relevant intervention. This method will ensure all post registration care is recorded with best possible accuracy.

The Sub-Committee received the response and no further issues were raised in this area.

   b. **Explain what additional purposes this proposed registry will fulfil that are not currently achieved by the national surgical infections audit,**
   c. **Confirm if there has been any previous correspondence with Public Health England and/or HQIP around potential crossover with existing audit programmes.**

The applicants explained that the current Public Health England Programme related to surveillance of surgical site infection. In the context of bone and joint infection this relates to infection after fixation of long bones, joint replacement surgery and neck of femur surgery. This programme only surveys the incidence and prevalence of infection after surgery. It has no remit involving the treatment and management of these infections beyond diagnosis after initial surgery. Furthermore it has no remit on native bone and joint infection. The applicants confirmed that, as such, there had not been any communication with PHE or HQIP.

The Sub-Committee received the response and it was agreed that this had highlighted the differences between the proposed registry and existing audit work facilitated by Public Health England. No further issues were raised in this area.

2. **Further information is required around the data flows and proposed linkages within the project – response should be provided, addressing the following points:**
   a. **Confirm how often it is proposed to facilitate data linkage with the HES dataset held by NHS Digital and detail what information will be returned when linkage is undertaken,**
   b. **Clarify whether there has been any correspondence with NHS Digital around this proposed data linkage and provide an overview of this,**

The applicants confirmed that they would only undertake linkage via HES for those patients who have provided informed consent to this element. As such, an application to facilitate this linkage would only be made to NHS Digital once patient's had been registered and provided consent to their ongoing inclusion in the registry.

The response was received and no further issues were raised in this area.

c. It is unclear whether data sharing agreements have been drawn up between the organisations involved in the project, i.e. Dendrite, participating Trusts and NHS Digital – provide confirmation and copies of any documentation where appropriate, to provide an overview of the various responsibilities within the project.

The applicants provided a draft data-sharing agreement for consideration by the CAG which outlined the proposed format.

The document was received and no further issues were raised by the Sub-Committee.

3. Further information is required in relation to the exit strategy to move away from support under the Regulations for the registry – response should be provided addressing the following points:

a. A more definitive plan should be provided in relation to future data linkages, providing detail of what data sources it would be anticipated that the registry would seek linkage with and for what purposes,

b. Consider others ways in which the identifiability of the dataset retained could be reduced,

c. Provide a more definitive plan in relation to the anonymisation of the dataset,

d. Consider ways in which a consenting mechanism could be developed for the registry, to enable an exit strategy from support under the Regulations to be achieved through consent.

The applicants confirmed that seeking patient consent was the basis of the exit strategy from holding confidential patient information with support under the Regulations. The applicants explained that, following the acute phase of the illness, patients are frequently cared for in the outpatient setting where seeking patient consent is more feasible. The applicants confirmed that they intended to seek patient consent once their treating site had advised that the patient was suitably recovered from their acute admission and treatment. It was confirmed that the registry team would undertake the process of seeking informed consent from patients. It was confirmed that the aim would be to complete this within an upper limit of 18 months from entry into the registry. However, it was noted that the plan was to seek consent as early as possible from patients – most likely within six months of registration.

Patients would be asked about on-going participation, collection of patient reported outcome measures and data linkage. Those patients who do not wish to participate would be asked about the use of data already collected, use of routine data or complete withdrawal from the registry.

Where to contact with patients within the 18-month window from registration was not possible, the applicants confirmed that their data would be anonymised permanently and no linkage would be performed. This process was outlined in the revised application form. The applicants also provided a consent form for review, which would be appended to the patient information sheet.

The Sub-Committee received the response and supplementary documents. The establishment of the exit strategy from support under the Regulations was commended. No further issues were raised in this area.

4. Public and Patient Involvement and Engagement – provide a detailed plan of how activity in this area will be continued as the project progresses and the registry is established.

The applicants confirmed that a patient representative would be appointed to the registry steering committee. In addition, patient feedback on the process of registration and consent would be sought. It was also clarified that patient facing pages would be made available on the registry website, which will be designed with support from patient representatives.

The response was received and Members commented that the information provided did not provide the detailed plan of patient and public involvement and engagement activity which was expected. The Group agreed that this additional requirement should not delay the project from commencing; however, it was agreed that submission of a thorough strategy would be required as a six-month interim report. This would need to provide a detailed plan of what activity would be undertaken at various time points as the project progressed, in order for structured feedback to be given.

5. **Patient Notifications and Dissent – revise the documentation as follows to address the outstanding issues:**
   a. **Patient Information Leaflet – revisions should be made to the document as follows:**
      i. **Revise the list of confidential patient information items to include details of all patient identifiers which will be collated within the registry,**
      ii. **Provide a clear and accurate overview of the organisations involved with the registry, explaining who will have access to the data and in what format (identifiable, aggregated anonymised etc.) and what it will be used for, including an overview of links with wider NHS datasets.**

The applicants submitted a revised information sheet for consideration.

The Sub-Committee considered the revised information sheet and it was noted that the document appeared to relate to the consented information, rather than the initial entry into the registry. It was agreed that further revisions would be required to explain how and when patients are entered into the registry and provide an overview that consent is sought for continued participation. Members confirmed that the required revisions should not delay the project from commencing, but it was agreed that submission of a revised document would be required at the six-month interim report. Engagement with patients and the public should be undertaken to improve the document and ensure that this was accessible to a wider public audience.

   b. **Poster – revisions should be made to the document as follows:**
      i. **Provide a clear and accurate overview of the organisations involved with the registry, explaining who will have access to the data and in what format (identifiable, aggregated anonymised etc.) and what it will be used for, including an overview of links with wider NHS datasets.**

The applicants submitted a revised poster for consideration.

Members considered the document and it was agreed that further revision was required. It was noted that the document incorrectly stated that ‘no one’ would have access to confidential patient information, which was not accurate as administrative staff performing the pseudonymisation process would have access to the complete dataset, as referenced at section (q) of the application form. The CAG agreed that this reference required revision. It was also commented that it would be helpful to explain within the section entitled ‘Patient Consent’ that consent was being sought for ongoing participation, rather than initial inclusion. The Group agreed that this should not delay the project from commencing and confirmed that the revised document could be provided with the six-month interim report.

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 and Public Involvement and Engagement – submission of a detailed overview of activity planned in this area is required as an interim report within six months of the date of this outcome. Defined activities should be set out within a specific timescale to enable structured feedback to be gathered.
2. Patient Notification Materials – revisions are required to the patient-facing documents, which should be informed by the patient and public involvement and engagement activity. Revised documentation should be submitted for CAG review within six months of the date of this outcome.
    a. Patient Information Leaflet – requires revisions to provide a clearer explanation of when patients are included within the registry, and to explain that consent would be sought at a future date around continued participation,
    b. Poster – requires revision to accurately articulate who will have access to confidential patient information when data is entered into the registry and to provide a clearer explanation of the consenting procedure.
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed Dendrite Clinical Systems & Northumbria Healthcare NHS Foundation Trust, Version 14.1, 2017/18, shows a reviewed grade of satisfactory)**

Reviewers:

Name	Capacity
Dr Tony Calland MBE	Chair
Ms Sophie Brannan	CAG Lay Member
Mr Anthony Kane	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Liverpool Lung Project**

CAG reference: **18/CAG/0041**

IRAS project ID: **237861**

REC reference: **97/141**

Context

Purpose of Application

This application from the University of Liverpool set out the purpose of medical research with a focus on improving the early detection of lung cancer at an earlier and more curable stage. The Liverpool Lung Project (LLP) has been active since 1997 with participants providing informed consent to their involvement. This observational study investigates differences between lung cancers to identify opportunities for improving diagnosis or treatment. The LLP is primarily funded by the Roy Castle Lung Cancer Foundation and is one of the largest prospective lung cancer case-control and population cohort studies in Europe, recruiting mainly in Liverpool, but more recently also in Blackpool. 13000 participants have been recruited into the study: approximately 8000 healthy volunteers and the remainder patients recruited via collaborating NHS GP practices and hospital sites. Recruitment remains active for the project, to ensure that the study population reflects current medical practice and remains relevant. The LLP protocol was updated in 2015 and extends to June 2021.

At recruitment, following informed consent, lifestyle and clinical history data is collected by questionnaire and blood samples are taken. Additional tissue samples were taken with participant permissions. Clinical and outcome data is also collected (from hospital records and NHS Digital) as part of the follow-up procedures for participants.

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

Rationale for CAG Referral

The project first received a favourable ethical opinion in October 2017 and was subsequently granted ‘HRA Approval’ back in August 2016 and operated on a fully consented basis. The applicants had made a request to NHS Digital to link the study cohort with HES, ONS mortality information and cancer registration information.

An assessment was made by the Data Access Request Service (DARS) team at NHS Digital that the consent which was in place did not provide an adequate legal basis to support the proposed data linkage. The applicants were advised to submit an application to the CAG to seek support under the

Regulations in relation to the data processing and linkage in relation to the participant cohort who were consented into the study between 1997 and 2017.

CAG Members noted a separate meeting was held between NHS Digital and a sub-committee of the CAG during the processing and review of this application, which focussed on the broader referral process from NHS Digital when an assessment of the consent materials provided to support a submission had been deemed as no longer valid to support the data linkage processes. The CAG was also copied into ongoing correspondence between NHS Digital and the applicant during CAG consideration of this application.

Confidential Patient Information Requested

Cohort

- All participants recruited to the Liverpool Lung Project between 1997 and 2017.

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

- Name – validation
- NHS Number – linkage,
- Date of Birth - linkage,
- Date and cause of death – provided by NHS Digital for analysis,
- Gender – validation ,
- Sub sector postcode – linkage and analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. It was acknowledged that the study had recruited a unique participant cohort and Members recognised that there was public interest in the follow-up activity defined in the study protocol proceeding.

Background to Submission

The applicants had made a submission to the Data Access Request Service (DARS) team at NHS Digital in order to facilitate linkage with the datasets relevant for the study follow-up procedures. The applicants were advised that some of the consent materials previously used in the project did not provide an appropriate legal basis to support the linkage; however, it was not confirmed which consenting materials were deemed sufficient. The applicants were advised to submit an application to the CAG to legitimise this data linkage process for all participants who were recruited between 1997 and 2017.

Practicable Alternatives – Assessment of Consent Materials

Members noted that the consent requirements under current and forthcoming data protection legislation placed a far higher threshold in relation to consent than that of the common law. In particular, members considered the context of the study, the documentation, and the concept of ‘reasonable expectations’ of the participant and what would potentially be their expectations when providing the original consent. It was not clear to Members whether the DARS team at NHS Digital had considered the consent satisfactory under common law or data protection, but assumed for the purpose of CAG consideration it was in relation to common law (as per the remit of the CAG).

The CAG assessed the study participant information materials and consent forms as part of their consideration. It was acknowledged that, since the project began, the information and consent materials had evolved and a number of iterations were considered by the Group. Members reflected in that discharging their responsibilities effectively, they have a statutory responsibility under the NHS Act 2006 not to recommend support to the decision-maker where an existing lawful basis could be utilised to satisfy the common law duty of confidentiality.

Having considered the history of the consenting process for the study, the Group agreed, taking into account 'reasonable expectations' of the cohort as informed by the entirety of the relevant information materials, that under the common law duty of confidentiality the consent which had been taken from participants from 2003 onwards was valid, and processing of information for the specified purpose would not involve a breach of confidentiality. The following specific consent items, as detailed within the study consent forms across the study duration, were determined by the CAG to provide a sufficient legal basis, in relation to the common law duty of confidentiality, to legitimise the proposed data processing:

- I give permission for medical and related records to be examined and information taken from them for confidential use in the LLP (cited within consent forms from 23/04/2003).

- I agree to provide data about my lifestyle, medical, occupational and family history and gives permission for medical and related records (eg medical registers) to be examined and information taken from them for confidential use in the LLP (cited within consent forms from 23/11/2009 V2).

- I understand that information held and maintained by the Health & Social Care Information Centre and other agencies keeping patient medical records may be used to help contact me or provide information about my health status (cited within consent forms from 23/11/2007 V7).

In line with this, support could not be recommended for the participant cohort recruited to the study from 2003 onwards as an alternative legal basis was already in place, and processing of the specified information could proceed using the existing consent as the lawful basis to avoid any breach of the common law duty of confidentiality.

The Group agreed that the consenting materials which had been utilised in the project from the commencement of recruitment to implementation of revised documentation on 23 April 2003 did not provide a sufficient legal basis, under the common law duty of confidentiality, to support the proposed data linkage to be undertaken by NHS Digital. The CAG made this assessment as the pre-2003 consenting materials did not reference access to data from patient's medical records. Members agreed to provide a recommendation of support in relation to this historic sub-cohort of participants, in order to facilitate the required linkage via NHS Digital to enable the study's follow-up procedure of participants to be enacted.

Justification of Identifiers

Members were assured that the items of confidential patient information requested were proportionate and appropriate to facilitate the proposed linkage.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. Members were content that the patient and public involvement activity which had been undertaken was appropriate to the project and supported the activity proceeding. No further issues were raised in this area.

Patient Notification and Dissent

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

The Group was content with the information which was available via the LLP website informing participants of how their data would be processed to achieve the project aims and raised no further issues in this area.

Confidentiality Advisory Group Advice Conclusion

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

Specific Conditions of Support

1. Support extends to the release of confidential patient information and subsequent data processing undertaken by NHS Digital in relation to the cohort of participants recruited from the opening of the study in 1997 to the implementation of revised consenting materials, brought into use from 23 April 2003. Linked data would be returned to the applicants for analysis.
2. Favourable opinion from a Research Ethics Committee **(Confirmed – in place since October 1997).**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed – NHS Digital acting as data processor).**

Reviewers:

Name	Capacity
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Unexplained visual loss following silicone oil removal in patients presenting with retinal detachment in the United Kingdom: results of a prospective surveillance study**
CAG reference: **18/CAG/0031**
IRAS project ID: **229763**
REC reference: **17/SW/0289**

Context

Purpose of Application

This application from County Durham and Darlington NHS Foundation Trust sets out the purpose of medical research with a focus on unexpected loss of vision following removal of silicone oil used to treat retinal detachment. This is a prospective study utilizing the BOSU methodology. The research will be carried out at the City Hospitals Sunderland NHS Foundation Trust.

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

Confidential Patient Information Requested

Cohort

All patients, aged 18 years and over, the following confidential patient information will be released by BOSU to the applicant:

- Local hospital number – to allow reporting clinicians to be able to identify patient,
- Month and year of birth –validation,
- Gender – analysis of demographic factors.

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 (Final)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed – 19 December 2017).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – City Hospitals Sunderland NHS Foundation Trust, Version 14.1, 2018/18, satisfactory grade confirmed by NHS Digital email 19/04/2018).**

Reviewers:

Name	Capacity
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Using primary care to increase uptake of the Bowel Scope Screening Programme in Yorkshire: evaluating paper and telephone based interventions**
CAG reference: **18/CAG/0049**
IRAS project ID: **225268**
REC reference: **17/LO/1723**

Context

Purpose of Application

This application from University College London sets out the purpose of medical research which aims to investigate whether GP practice based interventions can help increase the uptake of bowel scope screening in Hull and other parts of Yorkshire. Over a six month period, individuals due to receive their NHS Bowel Scope Screening invitation (identified through GPs) will be randomly be assigned to one of three groups with attendance monitored and compared between groups:

1. Usual care: no contact from GPs.
2. Primer and self-referral letter: A letter advising of the future delivery of a BSS invitation will be sent by the individual's GP, along with a locally tailored leaflet explaining the test. If the practice receives notice that an individual did not attend their appointment, a letter highlighting the self-referral process will be sent.
3. Primer and patient navigation: As above, a letter and leaflet will be sent ahead of the NHS BSS invitation. If the practice receives notice that an individual did not attend their appointment, a call to the individual will be made. This call will aim to identify and address personal barriers to uptake and, if appropriate, help arrange a new appointment. If no telephone contact is possible, a self-referral letter will be sent.

Support under the Regulations is required to facilitate groups two and three as the additional patient contacts which are detailed in these two options will involve sharing confidential patient information outside the direct care team without consent.

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

Confidential Patient Information Requested

Cohort

1. Patients aged between 55 years and 21 days and 55 years and 48 days at the time they are enrolled in the study, who are registered with a GP practice participating in the trial.
2. Patients will be excluded from inclusion in the study if they:
   a. Have had their large bowel removed.
   b. Have a stoma bag to collect their stool.
   c. Are currently being treated for inflammatory bowel disease (i.e. ulcerative colitis, Crohn's disease, etc.).
   d. Are awaiting heart surgery or who have had heart surgery in the last three months.
   e. Have been diagnosed with cancer (any type) in the last 12 months.

f. Are registered on their GPs clinical system as a type II objector/opt out.

The following items of confidential patient information are requested from the patient's GP record:

- Full name – to enable intervention materials to be sent,
- Full Address – to enable intervention materials to be sent,
- NHS Number – to facilitate linkage via NHS Digital,
- Gender – analysis,
- Ethnicity – analysis.

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 (Final)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed – project received a favourable opinion on 05/12/2017. Substantial Amendment received a favourable on 24/04/2018).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – MailaDoc Ltd. Version 14.1, 2017/18 confirmed satisfactory by email direct from NHS Digital on 18/04/2018).**