Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

22 February 2018 at Barlow House, Manchester

Group Members:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Professor William Bernal	Yes	
Dr Malcolm Booth	Yes	
Dr Tony Calland MBE	Yes	Chair
Dr Patrick Coyle	Yes	Vice Chair
Dr Lorna Fraser	Yes	
Dr Rachel Knowles	Yes	
Dr Harvey Marcovitch	Yes	
Mr Andrew Melville	Yes	Lay
Ms Gillian Wells	Yes	Lay

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor
Mr Kevin Ahmed	Observer – HRA Assessor

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introduction

The Chair welcomed Mr Kevin Ahmed, HRA Assessor, to the CAG meeting who was in attendance in the capacity of an observer, in order to gain an understanding of the CAG.

Apologies for Absence

Apologies for absence were received from Dr Rachel Knowles ahead of the meeting.

Declarations of Interest

Dr Lorna Fraser advised in advance of the CAG meeting that the Lead Statistician noted on application 18/CAG/0038 (Agenda Item 6.c.) was a colleague and had engaged in discussion with Dr Fraser around the proposal. The CAG agreed that this represented a conflict and Dr Fraser took leave of the meeting during discussion of the item.

2. APPROVAL DECISIONS

The following was shared with the CAG for information.

Secretary of State for Health and Social Care Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health and Social Care (SofS) agreed with the advice provided by the CAG in relation to the 25 January 2018 meeting applications.

It was noted at the meeting that the DH senior civil servant on behalf of the Secretary of State for Health and Social Care (SofS) had not yet confirmed agreement with the advice provided by the CAG in relation to the annual review which was considered for application PIAG 03(a)/2001, reviewed at 25 January 2018 meeting.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 25 January 2018 meeting applications.

3. CONSIDERATION ITEMS

a. 17/CAG/0060 – Breach Report

Context

Purpose of Application

This application from the University of Warwick sets out the purpose of medical research into the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) Process. The ReSPECT process aims to respect patient preferences and respect clinical judgement through shared conversations between a person and their healthcare professionals. The ReSPECT process is new for the NHS and needs to be evaluated because it is designed for use with all patients in all healthcare settings. It is designed to replace the Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) system and address issues with that system by placing a decision about whether a patient should or should not be for

cardiopulmonary resuscitation within an overall care and treatment plan for emergency situation. An evaluation with sites that adopt ReSPECT early will enable an assessment of whether the process is used successfully to address such concerns and to identify whether any changes to the process are needed.

One of its principal aims is to make sure people understand the care and treatment options that may be available to them and that may work in a medical emergency and allow them to make healthcare professionals aware of their preferences. Past experience (e.g. Liverpool Care Pathway) has highlighted the importance of testing any changes to the way things are done. This project plans to study how, when and why these emergency treatment plans are made and the effects they have on patient care. It will use a mixture of methods for collecting information to achieve this aim.

The project involves a number of work packages; however, only work packages WP1B and WP3 are within the CAG considerations. The research requires the research team to access the following information from the patients' clinical records:

- Information recorded on the ReSPECT form,
- Clinical justification for a ReSPECT recommendation,
- General information about the patient (e.g. demographic information, severity of illness measures, laboratory results).

This information will be linked by hospital based research staff to hospital held information on:

- NHS Safety Thermometer data for each individual patient
- Overall outcome for each individual patient (length of hospital stay, survival to discharge, discharge location type).

The data extraction will be undertaken by research nurses within the six acute NHS hospital sites for WP1 and WP3 in England. A diverse range of university affiliated and district general hospitals will be selected. The hospitals will also serve a diverse population consisting of different ethnicities in rural and urban areas.

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

Confidential Patient Information Requested

Cohort

The cohorts for each work package were described as follows:

Work Package 1B – will involve the data extraction from approximately 20 patients per site involved in the project, which will be purposively sampled from the patient records used within WP3. In the first participating Trust, the applicants will initially select up to 20 records to pilot the evaluation tool in the context of the ReSPECT process. At this stage, if it is found that the tool needed to be refined, a further sample up to 20 records would be selected for analysis. Analysis of these records will inform further sampling at the next Trust with analysis and sampling continuing in an iterative process across all six participating Trusts until there are no new changes in the pattern of consistency, transparency, and ethical reasoning. It is anticipated that there will be a total sample size of approximately 140 records, including those used in the pilot, accessed within this part of the project.

Work Package 3 – will involve all adult inpatients meeting the inclusion criteria on the specified date of data collection for the NHS Safety Thermometer audit data collection. The applicants anticipate that this will be approximately 500 patients per site, totalling at least 3000 patients.

The following items of confidential patient identifiable data are requested for the following purposes:

- Name – data linkage and to facilitate opt-out,

- NHS Number – data linkage and to facilitate opt-out,
- Hospital ID – data linkage and to facilitate opt-out,
- Date of birth – data linkage and to facilitate opt-out and truncated to age for analysis,
- District-level Postcode – for deprivation scoring in analysis,
- Gender – for analysis,
- Ethnicity – for analysis,
- Wider clinical information – for analysis.

Data will be extracted from patient records by research staff that will undertake the data linkage and return a pseudonymised dataset to the research team at the University of Warwick. Research staff at the hospital will retain a pseudonymisation linkage record.

Breach Report

The applicants notified the CAG of a breach on 30 November 2017, for which the formal breach report was received on 20 December 2017. This was initially considered by Dr Tony Calland in correspondence.

The formal notification report was provided, following which further queries were raised and it became apparent that two breaches had occurred as follows:

The research nurse did not fully redact all confidential patient information prior to sending the electronic record to the trial team at the University of Warwick,

An electronic record was sent from the research nurse to the trial team at the University of Warwick which seem believed had been fully redacted; however, the redaction had failed and some of the confidential patient information was visible upon receipt.

Confidentiality Advisory Group Advice

The Group considered the two breaches which had been reported and it was noted that the first was down to human error and the second a failing of equipment. The applicants had undertaken appropriate investigation and implemented steps to prevent further issues of this type.

It was noted that, in line with the HRA Breach Reporting Policy, the nominated decision-maker for the Health Research Authority had considered the information in advance of the meeting and was satisfied with the steps taken.

The CAG noted the report information and agreed that no further action was required.

4. RESUBMITTED APPLICATIONS

a. 18/CAG/0038 (Resubmission of 17/CAG/0201) – The Yorkshire Lung Trial

Context

<u>Purpose of Application</u>

This application from the Leeds Teaching Hospitals NHS Trust set out the purpose of medical research which aims to test targeted Low Dose Computed Tomography (LDCT) scans screening in community settings concentrating on deprived areas of Leeds. The intention is to randomise 55-80 year old smokers or ex-smokers to intervention or usual care groups prior to approach. The intervention group will be invited to assessment for a Lung Health Check (including LDCT screening for high-risk people) framed as a pilot health service.

The applicants intend to compare outcomes between the invited group and a usual care group, which won't be invited to take part or know that they are in a research study. By comparing outcomes with a control population, the true benefits (of reducing number of late stage cancers, and therefore lives saved) and possible harms (of over-diagnosis) of introducing screening in the UK will be assessed.

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

Confidential Patient Information Requested

Cohort

Smokers or ex-smokers, aged between 55-80 years old, who are judged to be at increased risk of lung cancer as estimated by three criteria within the Leeds CCG area. There a wider range of clinical inclusion/exclusion criteria which would need to be satisfied before a patient would be invited to participate.

The cohort will consist of 62,980 people randomised, of which the following is anticipated:

- 31,490 people allocated to the intervention arm to receive an invitation to a Lung Health Check LDCT screening (including LDCT screening for people at high risk of lung cancer)
- 31,490 people allocated to the control arm who will not be approached but are necessary to follow study outcomes
- 6,892 people attending for lung health check and undergoing LDCT screening

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

- Name – to invite participants, deleted after invitation process,
- Patient Address including postcode – for invitation process and retained for ensure validity of randomisation (audit to be undertaken 6 months from randomisation then deleted),
- Postcode – converted to index of multiple deprivation and retained for analysis,
- NHS number– validation of sample, identification and linkage and long-term follow-up,
- Date of birth – linkage and analysis and retained for long-term follow-up,
- Date of Death – analysis – full format,
- Cause of Death – received in ONS coded format,
- Postcode – analysis (Deprivation score) and intervention arm (facilitate invitation) and retained for all to facilitate long-term follow-up,
- Gender – analysis and retained for analysis,
- GP Registration (practice) – required for invitation process and retained for analysis,
- Named GP – required for invitation process and then deleted,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

This application was a resubmission of 17/CAG/0201, which had previously been considered by the CAG at the meeting on 07 December 2017. Members considered the applicant's response to the request for further information which had been requested as part of the previous 'No Recommendation' outcome.

Public Interest

The CAG was satisfied that this application defined a medical purpose through it fulfilling a medical research purpose. The applicant provided further information to the queries raised around the public interest in the activity. It was confirmed that, as yet, there was no plans to roll out low dose CT scanning as a national screening programme for lung cancer detection. A letter from Professor Anne Mackie, Director of Programmes for the UK National Screening Committee and Director of Screening at Public Health England (dated 4th January 2018) which confirmed this position. The CAG assured following receipt of these further

clarifications, that the application was within the public interest as the outcomes from the trial would provide further evidence to support the potential benefits of low dose CT screening as screening tool.

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 acknowledged that over 62,000 patients would be included in the trial, with approximately 6,892 patients receiving an invitation for a screening appointment and being provided with the opportunity to formally consent to the use of their data. The Group acknowledged that access to confidential patient information was required in order to establish the cohort of patients who were eligible to participate. It was agreed that seeking consent from the wider proportion of patients who would form the control groups was not feasible due to the sample size. Further work was requested in relation to the overall communications strategy for the project, which was considered as part of the 'Patient Notifications and Dissent' section below.

The applicants confirmed that any patient who is invited to attend a screening appointment, but declines consent to participate in the study would not be able to undergo the CT scan. It was acknowledged that the CT scan was a research procedure and consent was required to enable this to be offered. No further issues were raised in connection to this point.

The CAG acknowledged that patients who were invited to participate in the study would undergo a telephone interview to determine their eligibility to attend for a lung screening. It was recommended that, if an individual was invited to attend for screening, they should be informed as part of this call that they will be required to provide informed consent to undergo the procedure.

- Use of anonymised/pseudonymised data

The Group accepted that the trial could not proceed without access to confidential patient information without consent, as this was required to establish the cohort.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. Members commented that the additional information provided as part of the revised submission provided a much clearer overview of the patient identifiers required for project and clarified when these would be deleted. No further 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. The applicants clarified that the project was only funded for a six year period following commencement of recruitment, as such, support was requested up 2024. The applicants explained that it was anticipated that the project would receive further funding to enable a 10 year follow-up of patients enrolled in the trial; however, it was understood that an amendment would need to be requested at such time as this funding was secured, to extend the duration of support.

The data items retained to facilitate future follow-up had been reduced following guidance from the National Cancer Registration and Analysis Service at Public Health England. The applicants requested retention of

NHS Number and date of birth only to facilitate this follow-up. The CAG received the additional rationale and were assured that the applicants had taken the appropriate steps to reduce the identifiability of the data set which would be retained. It was noted that the database plan document had not been updated in relation to the changes which were described as part of the revised application. An updated document would be requested to ensure consistency across the documentation.

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 commended the work which had been undertaken by the applicants to improve the patient information materials and overall communications strategy for the project. It was confirmed that Type 1 and 2 objections would be applied prior to any data extraction from GP practices, to ensure any patients who had registered dissent would not be included in the project.

A revised GP practice poster was provided which had addressed the points raised via the previous CAG review. A wider series of information leaflets had been developed for specific circumstances which were raised during the previous review, including enquires from the general public about the project and specifically for patients who were invited to attend a screening appointment but declined to consent to participate in the study.

The applicants described a wider communications strategy which involved posters within community pharmacies and a series of advertisements in a local newspaper. It was also noted that wider information would be displayed on the study website which had been categorised by potential audiences. Copies of the text were considered by the CAG and no further issues were raised in this area.

The Group considered the revised participant information sheet and it was noted that revisions had been made to highlight the research purposes; however, this could be made more prominent by including a reference within the opening paragraph of the document. This minor revision would be requested. The Group was satisfied with the wider documentation suite and no further issues were raised.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. The Group acknowledged that the overall proposal had now received a favourable ethical opinion and was satisfied that previous concerns around the trial methodology had been addressed. It was acknowledged that revised patient information materials would be submitted to the REC as a substantial amendment following the CAG review. Evidence that these revised documents had received a favourable ethical opinion prior to a final recommendation of support being issued for the project.

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. Revise the database plan diagram to ensure consistency with the revised data retention periods described within the revised application.

2. Confirm that patients will be advised as part of the screening eligibility call that they will be required to provide informed consent to undergo the CT screening scan.
3. Revise the 'Patient Information Leaflet' to include a reference to the research purposes within the opening paragraph.

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

Specific Conditions of Support (Provisional)

1. Support is recommended for the initial six year period for which the study is currently funded. Any extension to this duration would need to be submitted as an amendment as such time as additional funding is secured.
2. Favourable opinion from a Research Ethics Committee. **(Pending – overall proposal received favourable ethical opinion on 22 January 2018. Substantial amendment is required for review of the patient materials.**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed)**
   - **Leeds Teaching Hospitals, organisation code RR8, complies with the Information Governance Toolkit (v.14 2016-2017). Reviewed grade Satisfactory with a score of 78%.**
   - **University of Leeds – IRC, organisation code 8E218-IRC, complies with the Information Governance Toolkit (v14. 2016-2017). Reviewed grade Satisfactory with a score of 88%.**
   - **CFH Docmail LTD, organisation code 8HN70, complies with the Information Governance Toolkit (v14. 2016-2017). Reviewed grade Satisfactory with a score of 100%.**

5. NEW APPLICATIONS – Non-Research

a. 18/CAG/0039 – NHS Improvement Getting It Right First Time (GIRFT) programme

Context

Purpose of Application

This application from NHS Improvement set out the purpose of service evaluation to determine the specific causes of medical negligence claims as with surgical specialities through detailed case analysis. The programme aims to identify poor practice and influence national guidance to address to reduce the number of claims and improve patient care and experience of the NHS.

The purpose of the Getting It Right First Time (GIRFT) programme is to determine specific causes of clinical negligence claims against all NHS services from both medical and surgical specialities as well as all areas in which NHS Resolution receive claims in order to improve patient care. The GIRFT programme will also monitor the volume and cost of these claims to drive service improvements. The previous approved application (15/CAG/0144) for Royal National Orthopaedic Trust Getting It Right First Time (GIRFT) programme looked solely at surgical specialities.

The updated NHS Improvement GIRFT programme would like to access specific litigation data held by NHS Resolution on its claims management system. This reflects the Secretary of State for Health and Social Care extending the remit of NHS Improvement GIRFT programme, as part of the Lord Carter recommendations, to include over 34 specialities, both medical and surgical, and the role that both NHS Improvement GIRFT and Model Hospital teams are to play in order to help NHS Resolution and NHS trusts learn from claims.

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

Confidential Patient Information Requested

Cohort

- All individuals who have notified NHS Resolution of an intention to make a claim against an NHS Trust since 2003.
- An accurate sample size cannot be estimated from the outset of the project; however, it is stated that 57,761 claims have been made in the last five years alone.

The following items of data will be released from NHS Resolution to NHS Improvement:

- Patient age at incident,
- NHS Resolution Claim Reference and Claim ID,
- Sex,
- Description of medical negligence claim including dates of incident, date of case creation (notification), case status and outcome, damages paid, case costs, causes and injury sustained.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the proposed activity defined a medical purpose, as it proposed a service evaluation aimed at improving the provision of care through the management of health and social care services. The public interest in the activity was clear, as through analysis of historic claims, the programme aimed to identify poor practice and influence national guidance to improve patient care and experience within the NHS.

Remit of the CAG – Scope of Support

The remit under which the CAG can advise is defined in section 251 of the NHS Act 2006 and its Regulations, which enables the common law duty of confidentiality to be temporarily lifted so that confidential patient information can be processed for specific purposes, without seeking consent from the individual patient, and without the data controller being in breach of this common law duty. 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', and then also fall within the definition of 'confidential patient information'.

The Group was assured of the importance of the programme proceeding; however, it was acknowledged that further information was required in order to clearly understand how the proposed activity fell within the remit of the CAG. It was acknowledged that a similar application had received a recommendation of support in the past; however, it is a requirement for each application that the applicant clearly demonstrates why the activity described falls within the CAG's remit.

Members agreed that clarification was required around the information which would be provided, together with a clear statement from NHS Resolution, as data controller for the litigation files, as to why this information falls within the definition of confidential patient information. The Information Commissioner's Office (ICO) has developed an Anonymisation Code of Practice, which should also be taken into account, when describing how the information to be disclosed falls within the definition of confidential patient information.

An example of a full dataset which could be included within the litigation files would also be required to understand what the dataset comprised of as a whole. As the remit of the CAG extended to confidential patient information only, it was unlikely that a recommendation of support would extend to the full litigation

file dataset, which it was expected may contain information in relation to staff or third-parties and legal advice, as examples, which would be out of scope for the CAG through not fulfilling the definition of patient information.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The Group was assured that consent was not feasible for this activity, due to the volume of historic claims which will be considered within the programme.

- Use of anonymised/pseudonymised data

The applicants had historically attempted to use aggregated data to undertake the activity in a similar programme; however, it was found that this did not provide sufficient clinical information to achieve the programme goals. It was acknowledged that no direct patient identifiers had been requested as part of the programme.

Data Transfer and Access Arrangements

Members were unclear how the data would be transferred from NHS Resolution to NHS Improvement and who would have access to the data files in order to undertake the analysis. It was agreed that further information would be required as part of the resubmission around the logistics of the data transfer and how this would occur. An overview of who would be involved in the analysis to gain an understanding of how widely the data would be accessed.

It was further queried how assurance could be provided that the litigation files which were transferred did not include any confidential patient information. Further information was required to understand how the litigation files were redacted prior to transfer together with an assurance that no confidential patient information would be included in error.

The Group also queried what the current access controls were around the NHS Resolution database and what the agreed protocols were in relation to disclosure from this database.

Data Controllership Arrangements

The applicants had stated that NHS Improvement and NHS Resolution would be joint data controllers for the application activity. In order to fulfil the data controllership responsibility, an organisation must be registered with Information Commissioner's Office (ICO), to enable data protection registrations to be checked to ensure the organisations are covered to process information for the purposes as set out in the application. The two organisations detailed did not appear to be registered with the ICO under the names provided. It was acknowledged within the application, that applicants had referenced current data protection registrations for Monitor and the NHS Trust Development Authority; however, these registrations did not reference the organisation names specified by the applicants. It was noted within the application that NHS Improvement was an operational name for the organisation which brought together a number of bodies. Clarification would be required within the resubmission documentation of which organisations are acting as data controller for the activity.

Cohort Sample Clarification

The cohort had been described as all individuals who had notified NHS Resolution of an intention to make a claim against an NHS Trust since 2003; however, confirmation was required around the end date of the sample.

Justification of Identifiers

It was acknowledged that the applicants had not requested any direct patient identifiers as part of dataset required for the project purposes.

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 applicants had described interaction with the President and CEO of the Patient's Association, whom were both supportive of the activity proceeding. Members commented that there had not been any direct interaction with patients or members of the public in order to seek their views around the proposal. It was suggested that the Patient's Association may hold public meetings at which the applicants could attend to discuss the proposal and test the acceptability of using patient data in this manner. It further noted that Action against Medical Accidents (AVMA) was a charity focussed on assisting patients who had suffered a medical accident and could be helpful in establishing a patient and public engagement mechanism for the programme.

Members agreed that further work was required in this area to engage with patients and the public about the proposed activity. As part of the resubmission, an overview of planned activity in this area would be required, which should include details of how and when the interaction will be scheduled together with an overview of what information will be presented in order to test the acceptability of using the information within NHS Resolution litigation files for the purposes of the programme.

Patient Notification and Dissent

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

It had been stated that a patient notification specific to the proposal would be made available via the NHS Improvement and the Getting it Right First Time Programme websites; however, this did not appear to have gone live at the time of application review. The Group agreed that sight of this information was required as part of the resubmission. It was noted that this should provide a clear overview of the programme, together with a summary of the data which would be provided to facilitate this. Explanation should be provided around the risk of re-identification from the data which is shared and explain why support under the Regulations is required to enable the activity to proceed.

The applicants had requested that the right to opt-out be waived for the proposal as it was not possible for any service user to opt-out without making the study non-viable as any opt-out could lead to the whole study starting again. Members were not assured by this rationale as it was acknowledged that analysis would initially be undertaken on a case-by-case basis. It was agreed that the notification materials should include a mechanism by which a patient could opt-out of their data being used in the programme. It was suggested that the opt-out mechanism could be advertised with a lead-in time to enable objections to be raised prior to data release from NHS Resolution. Consideration should be given this point. An overview of how a dissenting mechanism would be offered for the project would be required as part of the resubmission.

A query was raised in relation to the linked application which had previously been supported as one of the conditions of support which was attached to this previous recommendation was around the requirement for provision of a patient opt-out. In response to queries raised in relation to the proposed application, the applicants had stated that opt-out was not considered for the previous project as patient opt-out was not considered to be a significant issue for the work bearing in mind the level of data being provided by NHS Resolution; however, it was also stated that no patient objections were received. Members were unclear from the information provided whether the patient opt-out mechanism which had been stipulated as a condition of support for the previous programme had actually been provided. Further information was required in this area.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further Information Required (Summary)

The CAG was supportive of the application activity; however, the following information should be provided to allow the CAG to continue their consideration of the application:

1. Provide a clear overview of how the information which will be disclosed from NHS Resolution falls within the definition of 'confidential patient information' as set out in section 251 of the NHS Act 2006. This should be supported by NHS Resolution, as data controller for the information to be released.
2. Provide an example of the complete dataset which would be included within the litigation files to enable a determination to be made around the data items which would fall within the remit of the CAG.
3. Provide further information around the data access controls which are in place for the NHS Resolution database and what protocols are in place around disclosure from this dataset.
4. Further information is required to understand how the data would be transferred from NHS Resolution to NHS Improvement.
5. Confirm who will have access to the dataset within NHS Improvement.
6. Explain how the litigation files will be redacted of any confidential patient information together with assurance that this process is secure and effective.
7. Confirm which organisation(s) is acting as data controller for the application activity and provide the associated ICO Data Protection Registration reference number.
8. Confirm the end date of the cohort sample.
9. Patient and Public Involvement and Engagement – further work is required in this area to address the following:
    a. Provide an overview of a proposed patient and public involvement and engagement plan for the project,
    b. This should include detail around how the acceptability of using litigation file data for the project purposes would be tested,
    c. Consider how the Patient's Association or AVMA could assist in accessing a relevant patient cohort with which to engage.
10. Patient Notifications and Dissent –
    a. Provide a copy of the project specific notification, to include an opt-out mechanism, for consideration,
    b. Consider including a lead time to allow for meaningful opt-out,
    c. Provide an overview of how the patient opt-out mechanism will be managed.
11. Confirm in relation to the historic application that the provision of a patient opt-out mechanism, as stipulated in the conditions of support attached to the application, was operated and clarify how this was provided.

Once received, the information will be reviewed at the next available CAG meeting. Deadlines for future CAG meetings are available on the HRA website and you should contact the Confidentiality Advice Team to book the application onto the next available meeting.

6. NEW APPLICATIONS – Research

a. 18/CAG/0024 – POPStar (Pregnancy Outcome Prediction Study: Transgenerational and Adult Review)

Context

Purpose of Application

This application from the University of Cambridge set out the purpose of medical research to follow-up the families who had previously participated in the fully-consented POPS (the Pregnancy Outcome Prediction Study). The historic study recruited 4,212 women who delivered their first baby in Cambridge between 2008 and 2012. During their pregnancies, women attended for research scans, donated their blood and placentas for research, and allowed researchers access to the medical data surrounding their delivery. Over the last two years, the applicants have published the results of this study that have influenced health policy and pregnancy care.

The applicants currently hold for every mother who participated in POPS a very highly detailed record of the pregnancy and the baby's growth in the womb. The extensive information which is currently held in relation to POPS pregnancies provides a unique opportunity to understand how health in the womb influences later health outcomes.

The applicants are proposing linkage with data routinely collected by NHS Digital and the Department for Education to the POPS pregnancy records to find out more about the current health status of the POPS mothers and children, and their risks of experiencing disease. This will enable exploration of how pregnancy data can be used to predict the risk of adverse health outcomes (for example high blood pressure, obesity, diabetes or learning difficulties) in both mothers and children later in life. This is a prospective study which will perform annual data linkage for both the mother and child until the child turns 18.

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

Confidential Patient Information Requested

Cohort

The study will utilise the historical POPS cohort of 4212 mothers who gave birth to their first child in the Rosie Hospital between 2008 and 2012. The POPStar cohort comprises both mothers and their children, 8,424 individuals in total in the cohort, who did not withdraw from the study. The sample size is expected to decrease slightly after the study exclusion criteria had been applied.

The following items of confidential patient information will be required for both the mother and child for the purposes as set out below:

- Name – linkage and validation
- NHS number – linkage (NHS Digital only) and validation,
- Date of birth – linkage and validation,
- POPS ID – linkage and validation,
- POPStar ID – for linkage with historic data.

Wider clinical information will be provided by NHS Digital from the HES database to supplement details already held within the historic POPS trial database. Education attainment information will be provided from the Department for Education (children only).

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that this application defined a medical purpose through it fulfilling a medical research purpose. Members agreed that there was public interest in the activity proceeding, as it was acknowledged that the applicants currently held a rich data source on an established patient cohort, which provided a clear population for follow-up and exploration of the wider points described in the research application.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The applicants had advised that attempting to re-contact the patient cohort to seek consent for the follow-up trial was not feasible as this was a mobile population who were likely to have moved. It was explained that the applicants had attempted to re-contact a sub-cohort of the participants for a separate qualitative follow-up study of the original POPS trial. This previous attempt to follow-up up the participants had only achieved a 30% ascertainment rate. The applicants stated that, in attempting to seek consent from the participants for the proposed study, the integrity of the proposal could be significantly impaired by a similar low response rate. The CAG was assured by the applicant's rationale that consent was not feasible for the proposal.

- Use of anonymised/pseudonymised data

The Group was assured that the proposed data linkage could not be facilitated without processing of confidential patient information. Analysis would be undertaken on a pseudonymised dataset.

Scope of Support

Members acknowledged that linkage with the HES dataset had been clearly described with the application. The application referenced linkage with wider datasets held by NHS Digital; however, these had not been fully articulated. The Group was content to provide a recommendation of support to link the patient sample with the HES database only. Any requirement to link with wider datasets retained by NHS Digital would need to be submitted as an amendment to the application, together with a clear description of the purpose and public interest in the additional linkages proposed.

The CAG was also content to recommend support to the disclosure of confidential patient information to the Department for Education (DfE), to facilitate linkage with educational data. The remit of the CAG extends to confidential patient information only and as such, did not extend to the proposed disclosure from DfE. It was noted that it was the responsibility of the Department for Education as data controller for the educational data to ensure that a legal basis had been established to support this disclosure.

Cohort

The CAG sought further clarification around the proposed sample size numbers, as it stated that it was proposed that the same number of mothers and children would be included. Confirmation would be required from the applicant that this was accurate, as it was unclear whether there had been any multiple births within the cohort.

It was further queried whether the child cohort would be followed up until aged 16 or 18, as there were discrepancies between the study document. Confirmation of the follow-up period was required.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. The CAG was assured that patient identifiers requested were proportionate and appropriate to undertake the proposal.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicants were seeking support for annual data linkages until February 2029, when the youngest child reached 18.

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 agreed that the patient and public involvement and engagement activity which had been undertaken was appropriate and proportionate to the proposed activity. It was acknowledged that the feedback provided from this activity had led to the development of a 'frequently asked questions' document, which would be publicised on the study website. It was also noted that the applicants had incorporated ways to disseminate the research findings to interested patients. No further actions were required 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 CAG acknowledged that the proposed research was substantially different from the historic project which participants were formally consented into. The previous information materials had informed the patients that their participation in the study would end when they were discharged from hospital. It was acknowledged that, as part of the project, survival status for both mother and child would be checked on the NHS Spine. Members agreed that as this action had already been defined within the study protocol; updated contact details should also be collated for the mothers. This would enable a targeted correspondence to be sent to the most recent contact address to provide patients with the opportunity to opt-out to their inclusion in this follow-up study. An information leaflet had already been prepared for the participants. The applicants would be asked to provide agreement to this term, or if this was not deemed to be feasible, to provide a clear rationale to explain why this could not be taken forward.

Members were satisfied with the wider patient notification materials which would be available via the trial website.

Security Assurance at the Department for Education

The Group acknowledged that the Department for Education (DfE) would be acting as data processor for the project. As a non-NHS government body, the DfE did not undertake the IG Toolkit. The Confidentiality Advice Team reported that in previous projects where linkage and processing had been undertaken by the DfE, a bespoke IG assessment had been undertaken by NHS Digital to provide assurance to the CAG around the data security arrangements and similar evidence was required in this instance.

Research Ethics Committee Favourable Opinion

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

1. Clarify the cohort size, confirming the numbers of mothers and babies (accounting for multiple births) to be included in this study.
2. Confirm whether the children will be followed up to age 16 or age 18.
3. Patient Notifications and Dissent – it is requested that the following actions are undertaken to facilitate a targeted patient notification approach:
    a. When vital status is checked via the NHS Spine, updated address details are extracted for the mothers,
    b. Direct contact should be made at this address, providing a copy of the information leaflet, to enable any patient dissent to be raised,
    c. If this is not deemed to be feasible, provide response detailing a strong rationale to explain why this cannot be done.

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

Specific Conditions of Support (Provisional)

1. Support is extended to the linkage with the HES database within NHS Digital only. Any requirements to link the cohort with the wider datasets held by NHS Digital should be submitted as an amendment to the application.
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. **(Pending: Department for Education – outcome pending from NHS Digital assurance review. NHS Digital – shows reviewed satisfactory grade on Version 14, 2016/17).**

b. 18/CAG/0027 – Virtual Aneurysm Screening Project

Context

Purpose of Application

This application from the University of Leicester set out the purpose of medical research which aims to model outcomes of the Abdominal Aortic Aneurysm (AAA) screening programme based upon targeting men with a history of smoking; the only risk factor proven to influence the development of AAA. The study will include the records of men included within the screening cohorts from 2013/14 to 2016/2017 from the

NHS Abdominal Aortic Aneurysm Screening Programme (held by Public Health England), which will be linked with the primary care datasets: Clinical Practice Research Datalink and ResearchOne. Linkage will be undertaken by Public Health England.

The NHS AAA Programme operates with support under Regulation 5 of the COPI Regulations (application reference: ECC 3-04(0)/2011), to enable the relevant cohort of patients to be invited for screening. The patient cohort is all men in England in their 65th year who are registered with a GP. Support under the existing application extends to non-research purposes only to facilitate the screening invitation programme.

Screening outcomes (AAA or no AAA) will already be known in the smoking and non-smoking group. Secondary analysis will include testing other screening models (such as including prior cardiovascular events) and an economic, cost effectiveness analysis (using an existing economic model) for each model generated. This analysis will test the feasibility and cost-effectiveness of targeted screening for AAA in high risk groups.

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

Confidential Patient Information Requested

Cohort

- Men aged 65 who have been invited for AAA screening by the NHS AAA Screening Programme from April 2013 to March 2017 inclusive.
- It is estimated that there will be approximately 1 million men included within the cohort.

Public Health England will provide data from the NHS National AAA Screening Programme. Primary Care data will be provided from the Clinical Practice Research Datalink and ResearchOne. Public Health England is acting as the 'trusted third party' linking the datasets.

The applicant stated only NHS Number will be required to facilitate the linkage. This will be provided by all data providers to Public Health England in a pseudonymised format, with all data providers using OpenPseudonymiser to do this in order to facilitate linkage between the data sources.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that this application defined a medical purpose through it fulfilling a medical research purpose. Members considered the detail which had been provided within the application in relation to the 2015/16 screening programme – it was stated that 227,543 men were screened for AAA across this year; however, only 1.1% of this cohort were diagnosed as having AAA. It was also noted that the outcomes of the screening had particular implications for patients due to potential restrictions on a patient's ability to drive and fly, or seek health insurance, depending on the findings. The Group agreed that there was public interest in investigating the potential for a targeted screening programme, as set out in the application.

Scope of Support Required

- Change in Purpose of the Activity

Current support was in place under the existing application ECC 3-04(o)/2011 which extended to non-research purposes only in order to facilitate the invitation process for the AAA screening programme. Members recognised that the proposed application had been submitted to seek support to use the data which had been collated under this existing reference, for the additional purpose of research. The project had been designed in such a way that no confidential patient information would be disclosed in order to facilitate the additional linkage required to create the dataset needed for research analysis. The Group

acknowledged that whilst there was no flow of confidential patient information within the proposed study design, confidential patient information which had been collated with support under the Regulations would be utilised for a research purpose which was not currently supported. It was also noted that this confidential patient information would be used, albeit in a pseduonymised format, to create a wider clinical dataset than was currently available, solely for the purposes of the research project. The CAG recognised that the existing support did not extend to the research purposes proposed within the application or the linkage with wider primary care datasets and as such, agreed that support would be required under the Regulations to support the additional purpose described.

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 recognised the patient cohort to be included in the project was approximately one million patients and it was agreed that seeking consent from such a substantial group was not feasible.

- Use of anonymised/pseudonymised data

The CAG recognised that the project had been designed to operate under a pseudonymised at source approach, meaning that there would be no requirement to transfer confidential patient information to facilitate the data linkage. Analysis would be undertaken on the resulting pseudonymised data set.

Data Flows and Proposed Linkage

Members agreed that the information provided within the application around the data flows required to facilitate the proposed linkage was insufficient and would require clearer articulation in the revised application. It was commented that, whilst national screening programmes were undertaken on behalf of Public Health England, it was understood that data from the programmes was held by Northgate, a third-party organisation, whose involvement in the proposal had not been clearly set out within the application.

It was acknowledged that the applicants had removed The Health Improvement Network (THIN) as a data provider following submission of the initial application as methodological issues had been identified with linking data from this provider with the wider data sources providing information to the project. It was agreed that any references to THIN would need to be removed from the application upon resubmission.

The Group agreed that further work would need to be undertaken with the primary care data providers, CPRD and ResearchOne, who were involved with the study as it was understood that NHS Number was not held within these two databases and a clearer understanding was required around how the proposed linkage would be undertaken. Further information was also required around the wider clinical dataset which would be returned from these providers to support the research analysis.

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 study had been designed in such a manner that the identifiers had been limited to the use of NHS Number in a pseudonymised fashion.

Exit Strategy

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

that support had been requested to extend to the change of purpose for data collated with support under the Regulations. Whilst no confidential patient information would be used within the study, the applicant had cited that the research analysis was expected to take two years to complete and support under the Regulations would be required for the duration to support the research purpose.

National AAA Screening Programme – Patient Information Materials

The CAG recognised that Public Health England were responsible for the patient notification mechanism and associated information materials that supported the national AAA screening programme. As some of the aspects requiring clarification related to the information materials provided to patients upon invitation to the screening programme, it was agreed that PHE would be copied into the outcome.

The Group considered the patient information sheet, 'NAASP – How we use your personal information' (Updated August 2016) as part of the review. The document included four clauses for which permission was requested from the patient and it was stated that first three points had to be agreed to in order for the patient to undergo screening. The fourth clause which was included within the document stated that permission was sought '*To contact you, asking whether you will allow us to use your personal information for research purposes*'. It was acknowledged that the link provided within the document to the NHS Choices website also stated that patients would be asked if their information could be used to contact them in the future about research which was going on in the screening programme.

Members acknowledged that, from the detail provided with the supporting information materials, patients could reasonably expect to be contacted prior to the use of their data for research purposes. It was not clear from the detail within the application whether there was any routine follow-up as part of the screening programme with patients around this aspect, or whether it was the intention to override this requirement to contact patients.

Confirmation was required around whether there had been any follow-up with patients in connection to the use of their data for screening purposes. If this had been undertaken, an overview of the outcomes of this activity would be required for consideration, as it was likely that a proportion of the patients would have provided consent to the use of their data for research purposes. It was acknowledged that clarification in this area would be required from PHE, rather than the applicant, as this was in connection to the screening programme.

It was recommended that the guidance which had been established in conjunction with the Information Commissioner's Office (ICO) around managing response to requests for consent from patients be considered in this area. If there had been no attempt to contact the patients to discuss the wider use of their data, further information would be required to understand why this had not been taken forward, noting that this was the process as set out in the information material provided as part of the screening programme. If this contact which was set-out in the supporting materials could not be followed up, it was recommended that the information materials were revised to more accurately describe how patient data would be used.

It was noted that there was a discrepancy between the information sheet submitted with the application and that which was currently available via the NHS Choices website. The CAG considered the current version of the document which was included within the application submission. The document currently published on NHS Choices, marked as archived in October 2017, differed from the information sheet currently in use and included a statement around use of data when a clear legal basis had been established. Members recommended that the wording of the information sheet and supporting information published on the NHS Choices website should be revised to explain more accurately how patient data collated for the purposes of the screening programme would be used more widely by Public Health England and to include the detail around how a patient can raise an objection to the use of their data for research purposes.

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 when considering public interest considerations as to whether an unconsented activity should go ahead.

Members recognised the work which had been undertaken by the applicants in this area, which included interaction with 40 men and their partners at a forum around AAA screening. It was acknowledged that further work had been undertaken in a focus group with seven research-naïve men and women. There was discrepancy between the dates for the activity as referenced in the application form and protocol and Members were unclear when this was undertaken. From the feedback provided in relation to the patient forum, it appeared that the attendees were supportive of the project progressing.

The detail around the activity did not provide a clear overview of how the proposed study had been presented at these patient engagement events. It was unclear whether it had been explained to attendees that, as part of the screening programme invitation process, patients had been informed that they would receive contact about the use of their data for research purposes, but the intention was to proceed without making this contact.

The Group acknowledged the importance of the proposed research progressing but it was agreed that further work was required in this area to explore the acceptability of proceeding with the project having not made contact with patients around the use of their data for a research purpose. Should this activity be supported in future, the reasonable expectations of patients who were invited to the screening programme would be overridden which is why further engagement work with patients and public is key, to ensure that they would be supportive of this.

It was agreed that an enhanced programme of patient and public involvement would be required to support the public interest in the activity proceeding and overriding the previous information supplied to patients around the use of their data for research purposes. Members agreed that the activity would need to be representative of the patient population impacted, including various social and demographic groups, together with a wider geographical area. It was further suggested that interactions with appropriate charities may be beneficial in reaching a wider, but appropriate, patient audience. A clear overview would need to be provided which explained the proposed study, what patient data would be used, how this data was collected together with details of the information which was provided to patients at this time (i.e. that they would receive contact to confirm whether data could be used in research) and details around the positive and negative implications of this specific screening programme. Feedback would be required around the outcomes of this activity as part of the revised application submission. If the responses given were negative, the CAG will take this into account when considering whether support could be extended to this wider research purpose, or whether further actions were necessary.

Patient Notification and Dissent

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

Members acknowledged the applicants intentions to produce study-specific patient information materials; however, these had not been provided within the submission. It was agreed that copies of any information which would be used to promote the research would be required as part of the revised application, together with an overview of a wider communications strategy and explanation of how a project-specific dissent mechanism could be operated. It was suggested that linking with appropriate charities could be useful in widening the communications strategy.

The CAG considered the information materials which supported the AAA screening programme. It was found that a dissenting mechanism to the use of patient data for research purposes was not provided, as

the information sheets and corresponding text on the NHS Choices website stated that patients would be contacted around the use of data for research. It was agreed that a recommendation would be provided to PHE that this information is updated to provide an opt-out mechanism, in place of advising direct patient contact.

Research Ethics Committee Favourable Opinion

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

Data Protection Act 1998 Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with data protection legislation. Applicants must therefore demonstrate through the application that it is consistent with the DPA. The CAG considered the information provided within the application form to show compliance against the DPA principles. Members agreed that further information would be required to explain how the activity was compliant with principle six, which states that personal data shall be processed in accordance with the rights of data subjects as it was noted in response to this principle that any patient who dissented to the use of their data for research purposes would be excluded from the study. It was commented that the option to opt-out of research purposes did not appear to have been described to patients and further information was required in this area.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the CAG agreed that, whilst supportive of the proposal in principle, further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further Information Required (Summary)

The following information provides a summary of the additional detail which should be provided to allow the CAG to continue their consideration of the application. The above detailed summary of the Group's consideration should be referenced when formulating a response to the below points.

The following points should be addressed through submission of a detailed covering letter, together with a revised CAG application form and wider supporting documentation.

1. Use of Data for Research Purposes – further information is required in this area to address the following points:
   a. Confirm whether there has been any previous contact with patients who were invited to participate in the AAA screening programme to ask for approval for the use of their data for research purposes,
   b. If so, why is the process being changed now to override this contact,
   c. If not, provide further information to confirm how the proposed activity is compliant with principle 6 of the DPA 1998,
   d. For information only – you may wish to consider the 'Managing Non-Response Guidance' which was established between the CAG and the ICO, which is available via the HRA website at the following link: https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants/

2. Data Flows and Proposed Linkage – further information is required in this area to address the following points:

a. A clearer understanding should be provided of the data flows required to support the project, ensuring all organisations involved in the project are identified. This should be supported by a more detailed data flow chart.
b. It was acknowledged that The Health Improvement Network had been removed as a data provider for the project – all references to The Health Improvement Network (THIN) should be removed from the application and supporting documentation
c. Provide further detail around the proposed data linkage procedures for the study, together with confirmation from the data controllers involved, of agreement to the proposed methodology,
d. Provide a detailed overview of the wider clinical information required for research analysis which would be provided as a result of the data linkage.

3. Patient and Public Involvement and Engagement – a wider programme of activity is required to seek the opinions of patients which represented a wider geographical sample to include differing social and demographic groups. The following points should be addressed:
   a. An overview of the study should be provided, together with details of the information materials provided to patients at the time they were approached about the screening programme in order to seek views on the acceptability of using patient information for the wider research purposes, without making contact with patients to ask for their approval,
   b. Feedback on the programme of the activity undertaken would be required as part of the formal resubmission which should provide an overview of the work which had been carried out, how many individuals were approached and a summary of their characteristics, what information was provided to the attendees to inform them about the study, together with clear details of the outcomes,
   c. If the responses given are negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.

4. Patient Notifications and Dissent – further information is required to address the following points:
   a. Provide an overview of the study-specific communications strategy, explaining how and where information will be published to promote the study together with copies of the materials to support this,
   b. Provide a clear overview of how a study-specific dissenting mechanism would be operated for the proposal.

Recommendation:

The following point is included as a recommendation for PHE in relation to the patient information materials used to support the AAA screening programme. It is not a requirement for the applicant, in connection to this research project, to provide a response on the below as part of the resubmission.

1. It was recommended that the wording of the national AAA screening programme information sheet and supporting information published on the NHS Choices website should be revised to explain more accurately how patient data collated for the purposes of the screening programme would be used more widely by Public Health England and to include the detail around how a patient can raise an objection to the use of their data for research purposes.

Once received, the information will be reviewed at the next available CAG meeting. Deadlines for future CAG meetings are available on the HRA website and you should contact the Confidentiality Advice Team to book the application onto the next available meeting.

c. 18/CAG/0028 – Mixed methods evaluation of the Getting it Right First Time programme: improvements to NHS orthopaedic care in England

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-March 2017.
- 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

Public Interest

The CAG was assured that this application defined a medical purpose through it fulfilling a medical research purpose. It was agreed that there was public interest in undertaking the evaluation of the Getting it Right First Time programme.

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 that consent was not feasible due to the patient numbers involved in the programme.

- Provision of Data from the National Joint Registry

It was noted that the CAG had previously provided a recommendation of support for the flow of confidential patient information from NHS Digital to the National Joint Registry in relation to all patients with relevant OPSC4 codes. This data included HES, PROMS and ONS data. Members queried whether the applicants had explored whether it was possible for the National Joint Registry to supply the pseudonymised dataset required for analysis. If this was possible, this may present a practicable alternative to seeking support under the Regulations for the project. It was agreed that this point would be raised with the applicants for further information.

- Use of anonymised/pseudonymised data

It was acknowledged that, in the current project design, processing of confidential patient information was required to facilitate linkage. It was noted that analysis would be undertaken on a pseudonymised dataset.

Cohort

It was referenced in the application that the proposed cohort for inclusion may be extended to include patients up to 2018. Clarification would be required around the proposed start and end date of the patient cohort to be included in the project.

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 was assured that the patient identifiers requested were appropriate and proportionate to facilitate the linkage proposed.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Members were unclear why support was being requested through December 2020, when it was noted that the data would be pseudonymised much before this point. It was unclear whether NHS Digital were intending to retain a

linkage key and if support was being requested for this element. If this was the case, further justification would be required to support the retention on the linkage key.

Patient and Public Involvement and Engagement

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

Members considered the patient and public engagement activity which had been undertaken to date. It was unclear from the information provided whether the applicants had explored the use of confidential patient information without consent as part of this activity. The applicants had specified that further work would be undertaken in this area. It was agreed further information would be required in this area, specifically to explore this component of the overall programme and to test the acceptability of using confidential patient information without consent.

If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, or whether further actions are necessary.

Patient Notification and Dissent

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

The applicants had provided links to information which was available via the UCL and NIHR Collaboration for Leadership in Applied Research and Care North Thames websites. Members agreed that this information appeared to be more appropriately targeted at an academic audience, rather than the general public. It was also noted that an option for patient dissent was not offered. The applicants had stated that they were undertaking further work their patient representative and UCL and NIHR CLAHRC to establish a meaningful objection mechanism.

The Group agreed that patient-specific notification materials should be developed as part of the proposed engagement activity. It was agreed that a wider communication strategy would be required which was not just website-based. An overview of the communications strategy and consideration of the supporting documents, together with an overview of how the patient objection mechanism would be operated was required prior to any recommendation of final support coming into effect.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. The applicants had clarified in advance of the meeting that a substantial amendment would be submitted to the REC to seek ethical approval for the aspects of the project relating to CAG. Evidence of this favourable ethical opinion would be required before any final recommendation of support could be provided.

Confidentiality Advisory Group Advice Conclusion

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

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

Request for Further Information

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.
2. Confirm the start and end date for the patient cohort to be included within the project.
3. Clarify the duration of support which is required under the Regulations to support the processing of confidential patient information without consent.
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.
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.
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.

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

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee. (**Pending – confirmation of favourable ethical opinion of substantial amendment required).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - NHS Digital show a satisfactory reviewed grade on Version 14, 2016/17. University College London, School of Life and Medical Sciences show a satisfactory reviewed grade on Version 14, 2016/17).**

7. MINUTES OF THE MEETING HELD ON 25 JANUARY 2018

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

8. CAG CHAIR REPORT

The Chair's Report was received and noted by the CAG.

9. EDUCATION ITEMS

The Group discussed potential education items, which were recorded by the Confidentiality Advice Team for further consideration and progression by the Chair team.

10. ANY OTHER BUSINESS

The Confidentiality Advice Team reminded Members of the requirement to submit expense claims in a timely fashion, particularly as the financial year end approached.

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