Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

05 April 2018 at Skipton House, SE1 6LH

Group Members:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Ms Sophie Brannan	Yes	
Dr Tony Calland MBE	Yes	Chair
Ms Hannah Chambers	Yes	Lay
Dr Katie Harron	Yes	
Mr Anthony Kane	Yes	Lay
Dr Rachel Knowles	Yes	
Mrs Diana Robbins	Yes	Lay
Ms Clare Sanderson	Yes	Alternate Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Miss Kathryn Murray	Senior Confidentiality Advisor
Ms Juliet Tizzard	Observer – HRA Director of Policy
Mr Stephen Robinson (Agenda Items 4: a-c and 5: a-c)	HRA Corporate Secretary

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

The Chair introduced Ms Juliet Tizzard, recently appointed Director of Policy at the HRA to the meeting. Ms Tizzard was in attendance as an observer to gain a deeper understanding of the CAG review processes.

Mr Stephen Robinson was welcomed to the meeting during the consideration of the research application business in his capacity as nominated decision-maker on behalf of the HRA.

There were no apologies for absence or declarations of interest made.

2. APPROVAL DECISIONS

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

Secretary of State for Health and Social Care Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health and Social Care (SofS) agreed with the advice provided by the CAG in relation to the **08 March 2018** meeting applications.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the **08 March 2018** meeting applications.

3. CONSIDERATION ITEMS

a. Member consideration of HQIP handling of welsh data flows in application

Background to Item

The SSNAP audit had been operating under Regulation 5 support since 2012. In February 2018 HQIP identified, as part of a transfer to a new data processor, that data flowing from Welsh health boards and subsequent linkages had not been included within the approved application. HQIP were advised to confirm what the legal basis for this data flow and subsequent linkages had been, and noted that this data flow involved HQIP, the Royal College of Physicians, NHS Wales Information Services (NWIS) and NHS Digital. HQIP were also advised to separately contact the Information Commissioner's Office to discuss and confirm whether this involved a potential breach of current data protection legislation.

HQIP also provided two separate amendments as part of this item involving a) amendments to cover the ongoing holding of Welsh data already collected and linked, and future processing of new Welsh information, and b) a change of data processor. CAG advice and recommendation have been provided separately.

Members were provided with HQIP responses to queries, a copy of the notification to the ICO, and background information as to how the error had continued.

Confidentiality Advisory Group Advice

Public Interest

Members noted that the audit appeared to be providing a clear public benefit, and had appeared to achieve a number of improvements to patient care. Members agreed that HQIP had provided sufficient evidence that this was an important audit with a clear public benefit.

As a whole, members agreed that they were supportive of the audit and their focus for consideration was how this data flow had been occurring over a 5-year period, without this error being noticed by HQIP, particularly at time of annual review, and the other entities involved in the processing and linkages.

Members were also sympathetic to HQIP as it appeared this was a genuine error. However, the subsequent handling of the detail provided to the ICO, clarification that Welsh data was being retained in an identifiable

format, and separate correspondence regarding use of non-research data for anonymised research purposes, led CAG to agree that it was important to ensure there were appropriate measures being put in place for HQIP to assure themselves that applications are operating correctly under the appropriate support, rather than handling on an *ad hoc* basis. Members were also mindful of the HQIP data controller role for a large number of audits taking place under support, were sympathetic to the challenges this can bring, and therefore considered it critical for public confidence purposes that steps be rapidly taken to ensure there are appropriate assurances in place moving forward. CAG also noted these uncertainties were leading to the consequence that members had to defer the supporting amendments, despite being supportive in principle. Members agreed that they would be supportive of positive steps to be taken by HQIP in a proportionate, but timely manner to enable deferred amendments to be concluded.

Scope of support under Regulation 5 of the COPI Regulations 2002

Members clarified that where support is provided, it is constrained by the detail of the written application form, and there are boundaries around entities, purposes, data items and flows, in addition to adherence to the standard conditions of support. It remains the applicant responsibility to ensure they accurately describe the activities requiring support, and they are operating within the terms of the described support. Any changes should be reviewed and submitted as either an amendment or new application as considered appropriate.

As per the standard conditions of support, the approved confidential patient information can only be processed for the purposes specified. Processing includes holding and manipulating an identifiable dataset in order to anonymise it. Non-research activities are approved by the Secretary of State for Health and Social Care, while research activities are separately approved by the Health Research Authority; both decision makers receive advice from the CAG when making their decision. The outcome letter for supported applications provides a legal approval decision by the relevant decision-maker. Members advised that an appropriate audit would identify any affected applications that may combine both purposes, that could then be managed appropriately.

Flow of welsh data 2012 – to date – retention of identifiable information

Members reviewed the notification provided to the ICO and raised some concerns that the notification did not appear to be as accurate as it could have been. For example, it indicated:

Personal identifiers for patients admitted to Welsh hospitals for stroke are transferred to NWIS and NWIS then link with PEDW and pseudonymised data is returned to SSNAP.

The secretariat had raised a query with HQIP, asking whether the Welsh data currently held was now de-identified or pseudonymised. The response from HQIP confirmed the following:

"*the SSNAP team retain the original SSNAP Welsh data in identifiable format, however the linked data is stored separately in pseudonymised and de-identified form. The SSNAP staff have applied limitations around the identifiable data and do not access it, only the pseudonymised data*."

This appeared to members to conflict with the breach notification information provided to the ICO. It did not appear to the CAG that the ICO had been provided with an understanding that the Welsh data was currently held by the audit team in an identifiable format. The CAG had been informed at the time that the ICO had informally provided feedback that they did not consider this to be a significant breach, in light of the remedial measures to be taken. However, members were of the view that the ICO may not have understood the complete data flow. Members wished to discuss further with HQIP to understand the situation better and agree a way forward.

In reflecting the applicant view that the understanding had been that Welsh data was included within the support, members reviewed the original application and noted it contained the following regarding retention and deletion:

"patient identifiable data will not be retained on their records once record linkage has been completed".

Members were unclear as to the precise need for the audit team to retain identifiable information once linkages were undertaken, therefore members were surprised to see that Welsh data was currently retained in fully identifiable format, as it appeared as if it should have been deleted once linkages were completed. Members noted that they needed to understand whether the retention of identifiable information was in fact appropriate as this appeared to differ from the originally approved application, and linked to the supporting amendment (sub-reference 18/CAG/0073), in addition to understanding the retention arrangements of identifiable English data.

Assurance audits

In order to provide assurance both internally and to CAG, members advised that an audit should be undertaken of all activities under NCAPOP that have received support under Regulation 5 of the COPI Regulations 2002. Members indicated that most bodies are already undertaking or refreshing information reviews as part of separate GDPR preparations, and HQIP had indicated in their query response that audits were planned. Members advised that the following should be provided within 10 working days:

1. List of relevant approved application titles, references and HQIP contact details for each activity. This will form the baseline of the activity for CAG and the audit purposes, and so handling of any arising issues can be appropriately managed within the team.

b. ECC 6-02 (FT3)/2012 Sentinel Stroke National Audit Programme (SSNAP)

i. Welsh data flows

Context

Purpose of amendment

An amendment was submitted by the Healthcare Quality Improvement Partnership (HQIP), in their stated capacity of data controller for the National Clinical Audit and Patient Outcomes Programme (NCAPOP). These are a series of national audits, where support is provided to data processors acting on behalf of HQIP. HQIP does not physically process confidential patient information under this support, and contracts out the processing of confidential patient information, through tendering processes or other appropriate means, to awarded data processor(s).

Scope of amendment

The amendment set out the following requests; the first two relating to data already collected and processed under a different lawful basis:

1. Retention of Welsh patient level data already collected since 2012 and linked to PEDW and ONS.

2. Continuation of the processing of Welsh patient level data which has been submitted to SSNAP by health boards in Wales since 2012, and linked to PEDW and ONS,

The amendment confirmed that HQIP had erroneously believed that the flow of Welsh data was included within the approved application. Scope elements 1 and 2 had not previously been covered under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 due to non-inclusion within the approved application detail in 2012. HQIP responses to queries had clarified that for this Welsh data flow and linkage the lawful basis between 2012 to current day, to avoid a breach of the common law duty of confidentiality, was the ‘public interest’.

3. Support to cover the future flow of confidential patient information from Welsh health boards to SSNAP (the existing support provided to SSNAP was SSNAP's existing 251 approval only covers flows of data from English hospitals to SSNAP)

4. Support to cover the future flow of welsh patient identifiers in SSNAP to NHS Wales Informatics Service (NWIS), linkage with the Patient Episode Database for Wales (PEDW) data, and the return and onward processing of PEDW-SSNAP linked data by SSNAP. The same process is used by SSNAP for linking English patient level data to HES and ONS through NHS Digital. SSNAP has support for this process.

5. Support to cover the future flow of Welsh patient identifiers in SSNAP to NHS Digital, linkage with ONS data and the return and onward processing of ONS-SSNAP linked welsh data by SSNAP.

Confidentiality Advisory Group Advice

Public Interest

The CAG was satisfied the application activity was an important one and had as a whole yielded benefits in developing improvements to patient care. The CAG therefore accepted this, and focused their considerations on the basis of the practical handling of the activity. This consideration took place in the context of the broader issues raised by the flow of the Welsh data flow, taking place since 2012 under the lawful basis of 'public interest', prior to the applicant realisation that it had been erroneously excluded from the scope of the current application which covered only the flow of English data.

Amendment submission

This amendment was signed by the current data processor, the RCP, noting that HQIP has awarded future data processing from 29 June 2018 to Kings College London. This change in data processor amendment has not yet come into effect so the amendment was accepted from the current data processor, the RCP; although it was clear that although the RCP currently held Welsh data collected from 2012 that was subsequently linked, that this was not included within the current support. HQIP had confirmed that this processing and linkage of welsh data was taking place under 'public interest' considerations.

Welsh data already collected and linked

Members noted they had considered separately regarding the handling of applications operating within support.

Subsequent queries had asked whether the Welsh data was currently held in an identifiable format, or whether, following linkages, it had been pseudonymised/ anonymised. The response had confirmed that it was currently held in an identifiable format; acknowledging that it was not being accessed. Members were clear that holding identifiable information was still a form of processing. In particular, members were surprised to see it was still retained in an identifiable format. It was understood that HQIP had falsely believed the flow of data was included within the existing support, however the application indicated that identifiable information would be deleted once linkages had taken place. Considering data had been collected since 2012, members did not understand why it was still retained in an identifiable format. This raised questions for members as to the status of the English data, as based upon the written documentation it appeared that this was in contradiction to the approved application detail. Members indicated they would be supportive in principle of retaining the linked pseudonymised information, but needed to understand the rationale for the retention of identifiable information, both in terms of the current status, and the approach to English data.

In reviewing the breach notification provided to the Information Commissioners Office, members also identified that the notification did not appear to make clear that the Welsh data was currently retained in an identifiable form, and raised concerns that the information provided to the ICO may not have been as accurate as expected. Members wished to discuss this with the applicant to understand their position further as while reporting to the ICO did not involve information supported under the COPI Regulations, the

role of the CAG was brought in as part of the mitigation measures and potentially placed too much emphasis on the role of the CAG in seeking to rectify the issue.

Members agreed that they could not currently provide a recommendation on the points related to the holding of Welsh data collected since 2012. It was agreed that a meeting should take place with HQIP to understand better the situation with this specific element.

Members also noted that the applicant had indicated that the flow of Welsh data, once the error was identified, was legitimised by the 'public interest'. Noting previous legal bases are not within the remit of the CAG, the CAG did note that long-term and continual data flows should not typically rely on the 'public interest', and questioned why the applicants were not continuing to rely on it, but accepted that the Welsh data had been omitted from support by mistake and not deliberate action.

In relation to the final three parts of the amendment, while the CAG was supportive in principle, it felt there were outstanding queries to be resolved before it could reach a recommendation. In particular, CAG wished to receive assurance of the arrangements currently taking place under this reference for England and Welsh data, and it would raise these points at the forthcoming meeting.

Confidentiality Advisory Group advice conclusion

The CAG agreed that further information would be required and therefore advised recommending deferral while a meeting took place to discuss the issues raised.

Next steps

1. CAG agreed that it would be prudent to request an urgent meeting with HQIP, in order to establish a clear way forward with defined timescales, before it could recommend to the decision maker that it had received assurance that the applications were being handled appropriately. It is understood that a meeting will take place on 26 April with CAG to progress this discussion and so HQIP had a clear understanding of the requirements under Regulation 5.

ii. Data processor change from RCP to KCL

Context

<u>Purpose of Amendment</u>

The request sought an amendment for the currently supported Sentinel Stroke National Audit Programme (ECC 3-02 (FT3)/2012.

The amendment confirmed that the Royal College of Physicians (RCP) are contracted to deliver and manage the SSNAP programme by HQIP until 31 March 2018. As part of that contract, RCP act as the data processer of confidential patient information collected by the Sentinel Stroke National Audit Programme (SSNAP). The RCP have existing support to process the supported information for this purpose.

In January 2018, HQIP agreed a contract with Kings College London to take over the management and delivery of the SSNAP programme from 1 April 2018. As such, they will act as data processor to HQIP for SSNAP moving forward. However, HQIP has been unable to secure the necessary IG permissions to transition the audit across to Kings College London on 1st April 2018 as had been planned. HQIP has therefore extended the contract with RCP for a period of three months in order that they continue to have lawful basis to store and process the data without being in breach of the common law duty of confidentiality.

This amendment requested a lawful basis through support under these Regulations for the transfer of the data held by the RCP to Kings College London. The proposed date of data transfer from RCP to Kings College London has been agreed for Friday 29 June 2018. HQIP will maintain contractual arrangements with RCP until approvals / permissions have been provided via the CAG, and by NHS Digital and NWIS.

The amendment form and revised (tracked changes) application form was submitted to reflect the change in data processing arrangements. It was confirmed that there were no other changes to the detail of originally approved application, aside from the explicit mention of Netsolving as a sub-data processor.

Confidentiality Advisory Group Advice

Members noted that a change in data processor was typically an administrative change managed by the secretariat on receipt of the appropriate documentation. However, members considered this change at a full meeting in conjunction with two other submissions from HQIP (historical flow of Welsh data and prospective use) as the items were all linked to the same application and raised broader questions.

Members agreed that a change in data processor was in line with previous applications and presented no issues in itself. However, in terms of CAG providing advice, and its role to support public confidence in the appropriate use of confidential patient information, the CAG felt they could not recommend support at this time to the decision-maker due to the outstanding questions and assurances set out in other correspondence. CAG remained mindful of the proposed data processor change date and the importance of the audit; however, considered it critical that separate assurances and a plan of action was developed, prior to CAG recommending that support could come into effect. Members also agreed that it was likely that HQIP would seek to respond rapidly regarding the separate assurances.

The CAG therefore agreed to recommend conditional support, however, this would be on the recommended conditions that HQIP take relevant steps to provide assurances of an appropriate direction of travel in terms of ensuring they are operating within the terms of the approved support. It was agreed that a meeting should take place to discuss this with HQIP so they could understand the issues and provide any further contextual information as part of a formal response.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that the change in data processor was appropriate, however the following would need to be in place:

1. Following a meeting with CAG around sub-reference 18/CAG/0073, HQIP to provide a clear and satisfactory plan in line with those discussions. CAG will provide confirmation when this information is considered satisfactory.

2. Support will not come into effect any earlier than 29 June 2018.

Once received, the information will be reviewed by a sub-committee of members in the first instance. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

Specific Conditions of Support (*Provisional*)

1. Support does not currently extend to KCL processing of welsh identifiable and linked data collected since 2012.

2. Kings College London (Hosted Secondary Use Team/Project view) Assessment Report - EE133874 - SSNAP. A link was provided to this assessment report that showed NHS Digital had reviewed the self-assessed score of KCL and confirmed it as satisfactory on the website on 08 February 2018. An appropriate level of security assurance must be maintained continuously throughout the duration of this support.

4. RESUBMITTED APPLICATIONS

a. 18/CAG/0054 (Previously 17/CAG/0194) – The SUMMIT Study

Context

Purpose of Application

This study from University College London sets out the purpose of medical research to investigate the feasibility of introducing low dose computed tomography (LDCT) screening to a group of adults at high risk of lung cancer. Potential participants will be identified from their GP records by a member of the UCLH study team, attending individual practices, as current or ex-smokers between the ages of 55 and 80 years. Potential participants will be sent an invitation letter. A sub-group of patients will also be sent a separate paper questionnaire on screening uptake. Potential participants' information, including age, sex, ethnicity, smoking status, and index of multiple deprivation score and rank, will be collected and linked to LHC attendance data. By analysing those who attend and those who do not, the applicants hope to understand what factors might influence whether or not a participant attends a LHC. Uptake is one of the primary objectives for this study and it is essential to understanding the population impact of a future UK LDCT screening programme. The application has been made to the CAG in order to allow the research team access to GP record systems in order to identify and invite potential participants to the study.

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

Confidential Patient Information Requested

Cohort

1. Individuals aged 55 to 80 years within the North Central and North East London area, who meet either of the following criteria:
a. Have a history of at least 30 pack years of smoking (or at least 20 years duration), and if former smokers, have quit in the past 15 years
b. 6-year lung cancer risk of ≥1.3%.

A maximum of 100,000 patients from 600 GP practices will be invited to recruit 25,000 participants. If the enrolment figure is not achieved, the applicants state that there are further 25-50,000 patients in the geographical region who will be eligible.

In addition, all individuals eligible for invitation to the initial Lung Health Check appointment will be included in the uptake study (pseudonymised data on demographic characteristics and smoking status, and the screening uptake and behaviour questionnaire).

The following items of confidential patient information will be extracted from GP records for the purposes as described:

- Full Name and Title – to facilitate invitation,
- Date of Birth – translated to age for analysis,
- Full Address – to facilitate invitation,
- NHS Number – for linkage (undertake with consent),
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

The CAG acknowledged that this application was a resubmission of 17/CAG/0194, which was considered at the CAG meeting held on 23 November 2017, when a recommendation against the project was deferred

pending submission of further information from the applicants. A revised application and supporting documentation was provided for consideration by the CAG in response to the below request for further information.

1. **Further information is required in order to establish the public interest in the application activity – provide response to the below points:**
   a. **Clarify how the proposed research study will fit in with the roll out of low dose CT scanning as a national screening programme,**

The applicants explained that there was currently no planned roll-out of low dose CT scanning as part of a national screening programme.

The CAG accepted this clarification and it was acknowledged that this point had previously been confirmed. The Group was assured that the project would provide further evidence to support whether low dose CT scanning would be feasible and beneficial as a national screening programme and it was therefore in the public interest for the project to proceed.

   b. **Provide further detail around what elements of the study are funded by Grail Inc. and what involvement the NHS has in these,**

The applicants confirmed that, with the exception of a postdoctoral fellowship which had been awarded by Cancer Research UK to uptake the screening sub-study, all funding for the project was provided by GRAIL.

The clarification was received and no further issues were raised in this area by the Group.

   c. **Provide an overview of the publication arrangements for the trial results.**

It was clarified that the study outcomes would be published in medical journals and may also be presented to wider health professionals at conferences.

Members received the response and no further issues were raised. It was acknowledged that the REC favourable opinion was now in place for the project and no issues had been raised around the publication arrangements.

2. **Retention of data for non-responders – the duration that confidential patient information is retained on patients who do not respond to the invitation should be reduced to six months. Provide confirmation to this and revise documentation accordingly, or provide a stronger rationale to justify the extended 15 months retention period.**

The applicants explained that confidential patient information needed to be retained for the duration of the recruitment period to ensure that patients who have been invited to participate are able to respond at any time across the recruitment period. Operating recruitment on this basis would mirror the reality of a national screening programme. The applicants further advised that deleting confidential patient information at an interim period had the potential to cause confusion amongst patients who had been invited to participate, but their details could not be found in the recruitment system if they responded to the invitation outside of the six month period.

It was further confirmed that should the recruitment target of 25,000 patients be achieved before the 15 month recruitment period elapsed, the applicants would delete all confidential patient held for patients who did not respond to the invitation to participate.

Members were assured by the additional rationale that retention of confidential patient information for all patients who were invited to participate in the study was required for the duration of the 15 month recruitment period. The Group was satisfied that confidential patient information relating to individuals who did not respond to the invitation once recruitment was completed, either by the target cohort being achieved or the 15 month period elapsing would be deleted.

3. **Retention of demographic and clinical data for ineligible patients who attend the lung health check – this patient group should be asked to provide consent for the retention of the data gathered about them to the point at which they were deemed ineligible for inclusion in the full trial – provide confirmation to this point and submit the revised documentation necessary to support this revision. Alternatively, further rationale should be provided to support why these individuals cannot be consented for the retention of data which had been gathered about them to this point.**

It was clarified that at the point an individual declines to take part in the study or is deemed ineligible, their confidential patient information would be deleted from the study database and the individual would not be invited for any further engagement in the study. However, pseudonymised uptake data (age, sex, ethnicity, tobacco consumption code term and date, IMD rank and score, first part of postcode) would continue to be retained to enable the required analysis of the uptake to screening endpoints of the study. It was confirmed that patients were able to dissent to this retention should they wish.

The Group received the clarification and it was acknowledged that this information was required as part of the study analysis and patients were able to raise an objection to its retention. No further issues were raised in this area.

4. **Data storage arrangements – further information is required around the data storage arrangements for the trial as follows:**

a. **Provide further rationale to support why Amazon Web Services had been chosen for data storage facilities, over the standard NHS or University servers,**

The applicants provided further rationale to support the decision to operate the study database via Amazon Web Services. It was explained that the system would help to replicate how it was expected that the screening programme would work in reality. It was further explained that the complexities of the study and number of participants involved led to the decision that a cloud-based database solution was the most appropriate for the project.

The CAG received the further rationale and it was acknowledged that Amazon Web Services had begun the submission of an NHS IG Toolkit, in order to provide security assurance as per DH standards. No further issues were raised in this area.

b. **Clarify where the Amazon Web Services servers are located,**

The applicants confirmed that the servers were based in London, England.

The response was received and no further issues were raised.

c. **Confirm what the data controllership arrangements are in respect of data which is stored via Amazon Web Services,**

It was confirmed that University College London was the data controller for the pre-consent confidential patient information which would be held on Amazon Web Services. University College London Hospitals and Amazon Web Services are acting as data processors for this data. GRAIL is a software supplier, but does not act as a data processor for any pre-consent confidential patient information.

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

d. **Provide further information around why it would be necessary for employees of Grail Inc. to access confidential patient information when undertaking maintenance work on the database. Clarification was also required around where the data would be held which would be accessed by the GRAIL Inc. staff.**

The applicants confirmed that there was no intention for GRAIL employees to have access to pre-consented confidential patient information; however, it was conceivable that should the database fail and

maintenance work be required, information within the database may be visible. Any maintenance would be carried out by GRAIL staff based within the UK. It was confirmed that GRAIL employees would not be able to access any pre-consented confidential patient information.

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

5. **Patient Notification and Dissent – a system should be established to promote the study in the relevant public domain in order to inform potential individuals of the project and facilitate objections. The following points should be addressed:**

a. **Study-specific information should be displayed in participating GP practices to promote the trial activity,**
b. **Information should be displayed with a lead-in time ahead of data extraction, to enable patients to register an objection against the trial and prevent their data being shared with the research team,**
c. **Documentation should make it clear that the activity is for research purposes and that any objection raised would be in connection to the research project, not the national screening programmes,**
d. **Copies of the documentation to be used to facilitate this programme are required for consideration by the CAG, together with an overview of the communications plan detailing how this would be carried out,**
e. **Study website text should also be provided for consideration.**

A poster was provided for consideration by the CAG. The poster would be displayed in GP practices with a lead time of between four and six weeks prior to data extraction occurring at that practice. It was clarified that the information would be made available in the format preferred by the practice as it was acknowledged that some operate electronic screens rather than physical noticeboards.

The applicants also provided a copy of the study-specific webpage content for consideration. It was confirmed that the GP poster and participant invitation letter both included this website link to enable interested parties to find out further information about the study. Contact details are provided together with an explanation of how a patient can opt-out of their inclusion in the study or request that their data is deleted, if data extraction from their GP practice has already occurred. It was confirmed that any dissent or opt-out was in relation to this research project only.

The Group considered the response and supporting documentation. Members were satisfied with the communications strategy and dissenting mechanism; however, it was agreed that further work was required on the information materials which facilitate this.

It was agreed that the GP poster required further revision to make the research purpose very clear. It was agreed that this information would need to be included near the top of the document, so any reader would be clear that the activity was research-related. It was also agreed that the sentence which referenced UCLH researchers could be revised to clearly state that the appointments are part of a research study. Members agreed that sight of the revised poster would be required prior to any recommendation of support coming into effect.

The CAG also stated that the website text would benefit from revision to ensure that this was accessible to the everyday reader, as it was commented that the current draft used some sophisticated language which may not be understood by all readers. Sight of the revised website text would be required prior to any recommendation of support coming into effect.

6. **Submit a revised patient invitation letter to address the following points:**

a. **Clearly inform patients that non-response to the letter, in either a positive or negative manner, would still result in their confidential patient information being retained by the research team. Clear guidance should be given around how an individual can object to this.**

The applicants provided a revised participant invitation letter, which include additional information around the retention of information for the duration of the recruitment period. Additional information was also added which explained how a patient could object to this retention.

Members considered the revised information leaflet and it was commented that whilst the additional information did make it clear confidential patient information would be retained, it did not explain that this would be held by researchers for the purpose of the project. It was agreed that invitation letter should be revised in line with the detail which would be added to the GP poster, so receiving patients were clear that data would be held for research purposes. It was agreed that the revised invitation letter would need to be reviewed ahead of any recommendation of support coming into effect.

7. Evidence of a favourable ethical opinion from an NHS REC is required.

The applicants confirmed that the REC favourable opinion had been issued on 23 December 2017. It was acknowledged that the further amendments to patient-facing materials would need to be considered by the REC via a substantial amendment.

The CAG received the response and acknowledged that evidence of the REC favourable opinion for the revised information materials would be required prior to the final recommendation of support coming into effect.

8. Evidence of a satisfactory NHS IG Toolkit submission, as reviewed by NHS Digital, is required in relation all organisations which will be receiving or processing confidential patient information with support under the Regulations. Assurance in relation to Amazon Web Services remains outstanding.

The applicants confirmed that Amazon Web Services was progressing submission of an NHS IG Toolkit.

The response was received and Members agreed that assurance against the NHS IG Toolkit would be managed via the standard conditions of support attached to the support recommendation.

Recommendation

1. It is recommended that participant information materials are revised to update the references to the Health and Social Care Information Centre (HSCIC) to NHS Digital.

The applicants confirmed that the references made within the patient-facing materials had been updated.

The response was received and no further action was required.

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. GP Poster – revise the information included within the poster to include detail around the research purposes near the beginning of the document. The reference to UCLH researchers should also be revised to make it clear that their involvement is for research purposes.
2. Revise the study specific website text to ensure that the language is suitable and accessible to a wider patient audience.
3. Participant Information Letter – revise the document to make the research purposes clear and explain that data will be retained for this purpose.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed – 23/12/2017. Confirmation of the favourable opinion for the revised patient-facing materials is pending).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Pending – confirmation of NHS Digital's reviewed grade on Version 14.1, 2017/18 is required for the following organisations:**

- CFH Docmail Ltd,
- University College London,
- University College London Hospital NHS Foundation Trust,
- Amazon Web Services.

b. 18/CAG/0059 (Previously 18/CAG/0016) – Evaluating the effect of Community Mental Health services on the lives of people with mental health problems in England over a time of economic insecurity

Context

Purpose of Application

This application from the Administrative Data Research Centre at the University of Southampton sets out the purpose of medical research with an aim to explore if administrative data sources can provide reliable long-term data to study the real world experiences of people with mental health problems in England. The study aims to establish a cohort of patients who received community mental health services in England in 2006 via the Mental Health Minimum Dataset (MHMDS) and the Clinical Practice Research Datalink (CPRD).

The study aims to investigate the effect of long-periods of adverse economic conditions on the mental health of the population. This will be undertaken by linking previously collected data from various administrative sources about an established patient population. The study cohort will be established from those patients in England receiving mental health care as recorded in the MHMDS and CPRD extracts for the 2006/7 financial year. This cohort will then be followed up across a ten year period (to 2016/17 financial year extract) in order to establish a long-term picture of the mental health care services these individuals accessed, together with detail around their socio-economic status (provided by DWP data), wide patient characteristics (provided via CPRD) and mortality data. The aims to evaluate the impact the period of financial insecurity, caused by the 2008 financial crisis, has had on the lives of mental health service users.

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

Confidential Patient Information Requested

Cohort

- Participants who received community mental health services according to MHMDS and CPRD in the 2006/7 extract between the ages of 18 – 64, living in England.
- 3 sub-groups of patients will be created:
  1. Patients captured solely on the CPRD – receiving only primary care services,
  2. Patients recorded within both the CPRD and MHMDS – receiving both primary and secondary care,
  3. Patients captured solely within MHMDS – receiving community mental health services from a secondary care provider; however, it remains unclear whether these individuals are also receiving primary care mental health services.
- The sample size is unknown but it is estimated that the MHMDS will hold approximately 200,000 eligible records and CPRD 100,000; however, the crossover between the two is not known.

The data sources are:

- Mental Health Minimum Dataset (NHS Digital),
- Clinical Practice Research Datalink (NHS Digital),
- Department for Work and Pensions Administrative Dataset,
- ONS Mortality Data (NHS Digital).

The following data sources will be included in the study; however, are out of scope for the CAG consideration as they will provide aggregated data only:

- CQC Community Mental Health Service User Survey – aggregated data only
- NHS England – bed occupancy – aggregated data only
- DH Financial Mapping Data for Mental Health – aggregated 2006-12 data only

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

- Name – linkage,
- NHS number - linkage,
- Date of birth – linkage – age kept for analysis (query at death or time of care interaction),
- Date of death – analysis – in year/quarter format only,
- Cause of death – analysis,
- Postcode – linkage – kept as deprivation index for analysis
- Address – linkage,
- Government regional office – linkage and analysis,
- Sex - analysis,
- Ethnicity – analysis.

Wider clinical and demographic information will be provided by NHS Digital which will be supplemented by economic/benefits data from DWP for analysis.

Confidentiality Advisory Group Advice

The CAG acknowledged that this application was a resubmission of 18/CAG/0016, which was considered at the CAG meeting held on 25 January 2018, when a recommendation against the project was deferred pending submission of further information from the applicants. A revised application and supporting documentation was provided for consideration by the CAG in response to the below request for further information.

1. **Scope of the project – further information is required to address the following points:**
   a. **Confirm whether the proposal is a feasibility study only intending to explore whether the proposed linkage is possible and can provide a long-term dataset required to facilitate analysis of mental service users experience.**
   b. **If the proposal is also intended to cover the evaluation of mental health service users' experience, further information is required around how this proposed analysis will be undertaken, as the evaluation element is not clearly articulated in the current application.**

The applicants confirmed that they were seeking support for the full project. It was explained that the organisations which were providing funding were only taking financial responsibility for specific elements of the overall programme; hence the project was split into arbitrary phases, which appeared to have caused confusion during the initial review of the proposal. The revised application form provided detail in relation to the full project. This was supplemented by a document which provided more detail around the proposed methodology.

It was confirmed that the data negotiation and linking element of the study was funded by the Administrative Data Research Centre and descriptive analyses were funded by the Nuffield Foundation.

Funding still needed to be secured for some of the wider elements of the project; however, the applicants explained they were confident that they would achieve this, once the preliminary descriptive results were available.

The Group agreed that the revised application form and supporting documentation provided a much clearer overview of the project scope and methodology. Sufficient information had been provided around the methodology for the second phase of the project, but it was acknowledged that this would only proceed if the applicants were successful in securing the future funding to support this. Members were content with the additional information provided and were content to recommend support to the project.

2. **Patient and Public Involvement and Engagement Activity – further information is required in this area to address the following points:**
   a. **The outcome of the focus group work which has been undertaken to date is required for consideration,**
   b. **Provide an overview of how any feedback from this activity would be incorporated into the project was also required,**
   c. **Provide a planned overview of how patient and public involvement and engagement activity will be incorporated into the project as it progresses,**
   d. **It is recommended that the patient notification mechanism is explored with patients and the public to discuss wider methods of communications to promote patient notifications.**

The applicants provided a copy of a manuscript which had been submitted for publication in the Journal of Innovations in Health Informatics in relation to the focus group work which had been undertaken as part of the project planning. Information was provided around how the applicants had implemented the findings of the focus group. As the manuscript had not yet been published, the applicants requested that the results were not discussed or published outside of the CAG meeting.

The CAG acknowledged the sensitivities around discussing the findings of the focus group; however, the activity which had been undertaken in this area was commended. Members recognised the commitment of the applicants to implement the findings of the focus group into the project and it was agreed that the benefits of this work could be seen within the communications strategy which would support the project and the ongoing patient and public involvement and engagement activity. No further actions were required in this area.

3. **Patient Notifications and Dissent – the following points should be addressed:**
   a. **The information materials should be revised to include wider methods of communication to the public, e.g. email, telephone, postal.**

The communications strategy for the project had been informed by the outcomes of patient and public engagement activity which had been undertaken. Copies of the patient notification materials were provided for consideration, together with an overview of the ongoing plans to promote the project.

The CAG agreed that the work which had been undertaken to date and which was proposed as the project proceeded was exemplar. It was acknowledged that the objection mechanism was clear with the information materials. Members agreed that some of the language which was used within the information materials was quite complex and could be challenging to some readers. It was agreed that further work could be undertaken to improve the accessibility of the notification materials. The Group agreed that work should be undertaken with the projects established Service User Advisory Group to revise the documentation. A report would be required at the time of first annual review around the activity which had been undertaken together with submission of the revised materials.

4. **Provide a copy any correspondence from the REC, including the favourable ethical opinion, if available for consideration by the CAG.**

The London Bridge REC issued a favourable ethical opinion in respect of the project on 05 February 2018. A copy of the outcome was provided for information.

The correspondence 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. Patient Notification Materials – further work should be undertaken with the Service User Advisory Group to review the patient information materials which support the project to ensure the text is accessible to a wide patient audience. A report should be provided at the time of first annual review around the activity which has been undertaken in this area, together with copies of the revised information materials.
2. Favourable opinion from a Research Ethics Committee. **(Confirmed – 05/02/2018)**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – NHS Digital, Version 14, 2016/17).**

c. 18/CAG/0060 (Consolidation of existing applications PIAG 3-09(e)/2003 and PIAG 1-05(d)/2008) – EPIC Oxford

Context

Purpose of Application

This application from the University of Oxford set out the purpose of medical research. EPIC-Oxford is an open-ended prospective study of men and women aged 20 and above at recruitment, between 1993 and 1999 in the UK. The cohort was recruited through GPs and postal questionnaires and provided a blood sample Follow-up included postal questionnaires, diet diaries and linkage to NHS records for death, cancer registration and hospital admissions. The study is designed to examine effects of diet on long-term health, with specific focus on vegetarians. EPIC-Oxford is the only large prospective study in the world with dietary data and blood samples for a large number of vegetarians with linkage for the whole cohort to cancer diagnoses, hospitalisations and causes of death.

The application was submitted to consolidate and replace two historically supported projects: PIAG 3-09(e)/2003 and PIAG 1-05(d)/2008.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover the activities involving the processing of confidential patient information, as described in the application.

Confidential Patient Information Requested

Cohort

The cohort was recruited into the EPIC-Oxford study between 1993 and 1999, which included adult vegetarians and comparable non vegetarians who were living in the UK at the time of recruitment. 65,411 patients were recruited to the project.

The following items of confidential patient information will be required to facilitate linkage with wider NHS datasets:

- Study ID – for linkage,
- Name – for linkage,
- NHS number – for linkage,

- Hospital Number – to link with tissue samples,
- Date of birth – for linkage.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose of medical research. It was acknowledged that EPIC-Oxford was a long-standing project which provided a valuable resource to study of the impact of diet on patient health, which had an established publication history. Members were assured that the ongoing follow-up of this established patient cohort would be of a public interest.

Background to the Submission

The EPIC-Oxford study had two existing applications of support under the Regulations, PIAG 3-09(e)/2003 and PIAG 1-05(d)/2008. An amendment was submitted to these existing approvals in December 2016, at which stage it was recognised that a refreshed application submission was required to bring the project in line with current standards, through the completion of a research application.

Scope of Support Requested

The application presented sought to consolidate and update the activities which were supported under the two historic references and to extend support to cover the following four activities, which had previously operated under the legal basis of informed consent:

The applicant provided information, based upon advice given to them by NHS Digital, as replicated below.

1. Flow of patient identifiers from University of Oxford to the MRIS team within NHS Digital noting it had undergone a number of historical name changes,
2. Processing of confidential patient information (linkage & storage) by the MRIS team within NHS Digital,
3. Supply of linked patient data sourced from PDS (NHS data), cancer registration information (NHS data now controlled by PHE) and mortality (ONS data) to University of Oxford;
4. Processing of supplied data by University of Oxford.

It was acknowledged that the following three points were supported under the existing PIAG references. These elements of the application activity were not considered further by the CAG as the existing support for these elements would continue under this revised application reference.

5. Further linkage of patient data to HES data by NHS Digital,
6. Supply of linked patient data sourced from HES (NHS data) to University of Oxford,
7. Linkage and further processing of supplied data by University of Oxford.

Consideration of Scope (Elements 1-4) – Assessment of Consent Materials

The remit of the CAG extended to the common law duty of confidentiality only and an assessment of the previous information materials was made on this basis to understand what would be determined to be the reasonable expectations of individuals who had consented to participate in the study. The CAG cannot comment on this consent model in relation to the Data Protection Act 1998 or the forthcoming GDPR.

The Group considered the correspondence provided from NHS Digital dating to December 2016, which stated their position as ‘the consent is no longer sufficiently informed to provide an adequate legal basis for elements 1 – 4’. Members considered the information materials, questionnaires and consent forms which had been provided as supporting information. It was acknowledged that the remit of the CAG extended to the common law duty of confidentiality and an assessment of the previous information materials was made on this basis to understand what would be determined to be the reasonable expectations of individuals who had consented to participate in the study.

Members made reference to the consent section of the recruitment questionnaire (Reference: EPIC PQ2), within which participants provided their consent to participate in the study and gave their doctor permission to provide clinical information from their medical records. The same consenting information was also provided on the covering page to the baseline questionnaire (Reference: EPIC PQ1), which proceeded to request considerable information in relation to the patient's health and care and also included a tear-off slip for the use of the GP, in order to inform the study team of the patient's death. The supporting postal consent details were also referenced, as at Q54 it stated that the research aimed to study the relationship between diet and certain diseases, such as cancer, which are registered with the NHS. The patient was asked to provide their NHS number together with some additional supporting details to enable this information to be cross-checked.

The CAG was in agreement that the consent which had been provided by the participants at recruitment provided a legal basis under the common law duty of confidentiality for the data processing detailed at points one to four of the application elements referenced by NHS Digital. Members agreed that participants could reasonably expect the ongoing follow-up on their health information as this was within the spirit of the consent and in line with the clinical information they had provided. The Group was therefore unable to extend support to these additional activities, as an alternate legal basis existed for these elements.

Practicable Alternatives

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

- Feasibility of consent

Members acknowledged that participants had provided informed consent upon recruitment to the study, which had been followed up with further correspondence over the study duration. It was agreed that an attempt to re-consent all of the study participants was not feasible due to the cohort size and potential to introduce a bias into the study from failed contact.

- Use of anonymised/pseudonymised data

It was recognised that confidential patient information was required to facilitate linkage with wider NHS datasets, which could not be otherwise achieved.

Justification of identifiers

Members were satisfied that the items of confidential patient information detailed were appropriate and proportionate to the achievement of the required linkage. 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 CAG recognised that this was a longitudinal study, with funding secured to June 2020. It was acknowledged that confidential patient information will be retained until this point to facilitate ongoing linkage with wider NHS datasets. The applicants had informed that it was likely that additional funding would be received to extend the duration of the study past the current funding period. An amendment would need to be submitted at that time in order to seek support for the extended project duration.

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. Whilst the CAG recognised the ongoing engagement activity with a patient participant

panel within the Nuffield Department of Population Health at the University of Oxford, it was commented that the study would benefit from the involvement and engagement with the actual patient cohort included in the study. Members observed the applicants commitment to keeping the patient cohort informed of the study's progress through the use of newsletters and website updates and it was queried whether the option for involvement and engagement opportunities with the cohort could be promoted by these means.

The Group agreed that the applicants should progress this over the coming year with the intention of establishing a panel of patients who are within the cohort to engage with around the project. An overview of the activity which had been undertaken in this area, together with any feedback received from patients, would be required at the time of next annual review for consideration by the Group. If the responses given to the ongoing use of confidential patient information for the project purposes were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

Patient Notification and Dissent

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

The CAG acknowledged the ongoing work which had been undertaken by the applicants since the project had begun to keep the participant group informed of the study's progress. It was recognised that an objection mechanism was available via the study website which provided participants a number of options in relation to how their data could be removed from the study.

Members were satisfied that the activity in this area was appropriate and proportionate to the ongoing project; however, two additional suggestions were proposed to improve the current communications strategy. It was acknowledged that the website provided a postal address to enable contact with the research team – it was advised that the inclusion of a telephone number and email address would be more accessible. The Group agreed that the dissenting mechanism should be promoted in the next study newsletter, to ensure all participants are informed of this option. Members agreed that confirmation would be required at the time of annual review that these points had been addressed.

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. Application activity previously supported under the references PIAG 3-09(e)/2003 and PIAG 1-05(d)/2008 are now expired and have been transferred to application reference 18/CAG/0060.
2. All pre-existing conditions of support related to PIAG 3-09(e)/2003 and PIAG 1-05(d)/2008 remain applicable
3. The pre-existing annual review cycle remains applicable, with the next annual review to be received 4 weeks before 06/10/2018, and then on an annual basis to this schedule.

4. Support extends to the linkage with HES data held by NHS Digital and PEDW data held by NHS Wales Informatics Service
5. Support does not extend to linkage with ONS mortality information, held by NHS Digital or cancer registration information, held by Public Health England as an alternative legal basis of consent was in place to support this linkage.
6. Support extends to England and Wales only. Alternative arrangements are required for the processing of data within Scotland and Northern Ireland.

7. Patient and Public Involvement and Engagement – additional work should be undertaken to establish a patient panel from the participating patient cohort. A report should be provided at next annual review around the progress made, together with an overview of any feedback provided by patients. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
8. Patient Notifications and Dissent – confirmation should be provided at next annual review that the following points have been addressed:
    a. Alternative contact means, i.e. telephone number, email address, should be added to the website to make contact with the research team more accessible,
    b. The objection mechanism should be promoted in the next newsletter, to ensure all participants are informed of the right to dissent.
9. Favourable opinion from a Research Ethics Committee. **(Confirmed – favourable opinion under reference 02/9/090. Updated REC reference to be applied).**
10. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – NHS Digital and University of Oxford Cancer Epidemiology Unit, Version 14.1, 2017/18, satisfactory).**

5. NEW APPLICATIONS – Research

a. 18/CAG/0055 – Evaluation of Liaison and Diversion Trial Schemes in England

Context

Purpose of Application

This application from RAND Europe sets out the purpose of medical research which seeks to assess the impact of Liaison and Diversion (L&D) services. L&D services aim to identify people experiencing a range of vulnerabilities as they pass through the criminal justice system (CJS) to ensure their health and other needs are known about and that they are referred to appropriate services.

The proposed research aims to assess whether the National Model for Liaison and Diversion services has any impact on health services utilisation, conviction rates, diversion from the CJS and the timeliness of court processes. This will be achieved by looking at the records of individuals using L&D services in national databases: namely the Mental Health Minimum Dataset, the Improving Access to Psychological Therapies (IAPT) dataset and the Hospital Episode Statistics (HES) A&E dataset, which are all held by NHS Digital. The research design involves comparing outcomes reported in these datasets before and after an individual's participation in the L&D service and comparing those using the services to a similar group of people who did not. The study involves collecting data about service users, but does not affect their care in any way.

This information will be supplemented by wider information including the police national computer and courts records and drug treatment records; however these are out of scope for the purpose of the application submitted to the CAG, and these elements were not considered.

The evaluation looks at the L&D service in 29 sites in England, covering 11 wave 1 sites (where the National Model was rolled-out in 2014) and 18 Wave 2 sites (where the National Model was rolled out in 2015).

Referral rationale to CAG

The project received HRA Approval back in November 2017 and operated on a fully consented basis; however when the applicants made a request to NHS Digital to link with the above named datasets, the application was rejected by IGARD.

It was referenced in IGARD minutes and correspondence from NHS Digital that the consent provided did not provide an adequate legal basis. The rationale for the NHS Digital rejection was that the consent documentation did not contain a specific statement enabling withdrawal of consent.

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

Confidential Patient Information Requested

Cohort

- All patients using Liaison and Diversion services within the 29 sites which were recruited to the study and provided fully informed consent to their involvement,
- Sample includes 7,593 individuals (5,071 in the control group, 2,522 in the treatment group).

The following items of confidential patient information will be provided to NHS Digital for the purposes set out below:

- Name – linkage,
- NHS number – linkage,
- Date of birth – linkage and analysis,
- Gender – linkage and analysis.

Confidentiality Advisory Group Advice

Background to Submission

The study received a favourable opinion from the REC and was approved by HRA Approval in November 2017, to operate on a fully consented basis. Recruitment for the project was completed and all participants were fully consented into the study. The study involved following up participants via administrative datasets held by wider organisations, including NHS Digital. An application to facilitate this data linkage was considered by IGARD (Independent Group Advising on the Release of Data) at NHS Digital. IGARD did not approve the application for their purposes as the view had been expressed that the consent did not provide an adequate lawful basis, on the basis that it did not sufficiently inform the participants of their right to withdraw from the study. Following the outcome of the IGARD review, the applicants were advised to submit an application to the CAG in order to establish an alternative legal basis.

Members focused specifically on the referral rationale, namely a lack of explicit right of withdrawal in previous documentation, and whether the overall consent and information materials in place were sufficient to satisfy the common law duty of confidentiality. It was made clear that the CAG only considers issues arising from the common law duty of confidentiality, and does not directly assess data protection compliance.

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 IGARD 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. Members agreed that the documents were of a high standard and, in this instance, provided very clear information to participants around how their data would be used, which organisations it would be shared with and for what purposes.

Whilst it was agreed that highlighting participant right to withdraw at the point of recruitment was preferable, Members agreed that it was important to recognise that the information materials were clear at the time of original consented recruitment that participation was voluntary. Members further noted that the applicants had also implemented an update on the project website that promoted participant right to withdraw from the study.

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 debated in detail, 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 was valid, and processing of information for the specified purpose would not involve a breach of confidentiality. In line with this, support could not be recommended 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.

Confidentiality Advisory Group Advice Conclusion

The CAG recommended to the Health Research Authority that support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 was not required as a practicable alternative of consent, satisfactory for the purposes of the common law duty of confidentiality, was already in place. The consent was considered to remain valid in this specific context, therefore support cannot be provided where an alternative lawful basis is already in place.

b. 18/CAG/0061 – The role of medicines in the deterioration of health in frail older people in primary care

Context

Purpose of application

This application from the University of Hertfordshire set out the purpose of medical research to evaluate the effect of medication on the deterioration of health involving patients over the age of 65 classified as elderly frail. Frail older people are particularly vulnerable to the untoward effects of medicines due to changes in their bodies that come with age. These vulnerabilities to the untoward effect of medicines may result in medicines related problems (MRPs). Unresolved MRPs may lead to clinical decline or deterioration resulting in increased use of health care services such as increased use of accident and emergency, hospital and General practice services. Hence it is important to understand the nature and features of deterioration and the MRPs that are associated with these in primary care.

The project aims to evaluate and characterise the nature and features of deterioration due to medicines in older people presenting in and from the primary care setting; to identify current interventions used in practice in primary care setting to prevent such deterioration and to explore service providers perception of the practical use and success achieved by these interventions; to make recommendations to support primary care providers to minimise deterioration due to medicines in frail older people within the primary care setting.

Information will be collated on patients over 65 years of age admitted via accident and emergency, acute medical unit or short stay unit to a hospital ward during 2016 – 2017. Records will also be accessed from GP practices of patients over 65 years of age with greater than two interactions with the medical team between 2016 and 2017. There are two parts to the study a prospective section involving service providers where consent will be obtained and a retrospective section which is the focus of this application.

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

Confidential Patient Information Requested

Cohort

Patients aged over 65 years with over two interactions with GP staff or hospital admission between 2016 and 2017. Specific inclusion criteria detailed below:

Inclusion criteria for Hospital Patients:
- Patients aged ≥65 years
- Patients admitted through the A&E, AMU, and SSU or by direct referral to the elderly care ward, frailty ward, cardiology ward and medical ward.
- Patients on one or more medicines (one of which should be oral for the management of a chronic medical condition)as use of oral medicines for management of chronic conditions may predispose patients to greater risks of MRPs
- Patients with one or more chronic conditions
- Patients with a frailty assessment score of ≥4 using the Rockwood scale (Addenbrookes Hospital) or ≥6 using the Edmonton scale (Lister Hospital).

Inclusion criteria for General Practices Patients:
- Patients aged ≥65 years
- patients with 1 or more comorbidities,
- patients on 4 or more medicines one of which should be oral medicine for the management of a chronic condition
- Patients with two or more contacts with medical providers in the preceding one year.
- A set frailty score

348 patients will be recruited from each clinical setting – 1392 patients in total. There will be no linkage between information extracted from the hospital and GP settings.

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

- NHS number - linkage
- Hospital ID - linkage
- GP registration - linkage
- Name - linkage
- Date of birth - linkage
- Date of death – analysis and linkage
- Postcode – sub sector level – geographical analysis
- Gender - analysis
- Ethnicity - analysis

Wider clinical information will also be extracted from patient records for analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the proposal described an appropriate medical purpose through medical research. Members were supportive in principle of the project as it was recognised that this was an important research area; however, it was commented that there was a lack of clarity within the study documentation which would need to be resolved prior to any recommendation of support being provided. Whilst the Group could see that there was likely public interest in the project proceeding, it had to be assured that the project could deliver before support could be recommended.

The CAG recognised that the application process is complex and can be daunting to researchers inexperienced in the CAG process and it is suggested that an experienced researcher advised the student applicant so that this worthwhile research project can progress with the minimum delay.

Application – Scope of Support Required

The Group commented that there was some confusion within the application between the quantitative and qualitative aspects of the project. It was understood that the applicant was only seeking support in relation to the retrospective quantitative element of the study; however, some of the key areas within the CAG application provided response in relation to both elements of the study. The Group was unclear whether the classes of support which had been requested for the project had blurred the project elements. The response provided at this question should only reflect the support which is required for the application elements which the CAG is being asked to consider. The applicants would be required to reconsider the classes of support which are relevant to the application activity.

Cohort

Members agreed that the detail provided within the application around how the retrospective cohort would be established was unclear. A clear overview of this process would be required, including clarification around which individuals would be involved in this process and confirmation of whether these individuals were members of the direct care team. This additional information was required to establish which elements of the cohort establishment required a recommendation of support under the Regulations to legitimise the data access and processing which would be undertaken.

The Group also requested clarification around the inclusion dates for the sample as there was contradiction between various study documents.

Practicable Alternatives

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

- Feasibility of consent

The applicants had explained seeking consent from the large patient cohort was infeasible due to the time constraints on the completion of the PhD programme. It was also advised that there was potential for the patient population to have relocated since their care incident, as the sample to be included would be retrospective. Members acknowledged the justification which had been provided by the applicants and also stated that, due to the demographics of the patient population, it was likely that a proportion of the patients would now be deceased. It was agreed that consent was not feasible for the project.

- Use of anonymised/pseudonymised data

The Group acknowledged that access to confidential patient information was required in order to extract the dataset which would be used in analysis. The terminology used to describe the extracted data did not clearly explain the identifiability of the extracted data. The extracted data had been described at points as encrypted and the Group was unclear whether this would contain confidential patient information. Clarification was needed around whether the extracted data would be pseudonymised or anonymised. It was recommended that the applicants review the Information Commissioner's Office (ICO) Code of Practice for Anonymisation when making this assessment.

Justification of Identifiers

Members were unsure about the rationale provided to support the items of confidential patient information referenced within the application. It had been cited that a number of the data items were required for

linkage; however, it was understood that data would be extracted from patient records in a pseudonymised format with no intention to link with other datasets. It was unclear whether there had been some confusion around the requirements to justify the identifiers as it appeared that the majority of the data items requested may only be required to identify the relevant patient records to be accessed.

The Group agreed that the applicant would need to reassess the items of confidential patient information which were required to facilitate the project and provide a clear justification to explain why each data item was required.

Data Flows

The CAG was unclear of the data flows involved in the study. The data flow chart and supplementary information provided insufficient detail to provide a clear overview. Further information was required from the applicant to explain the data flows within the project. This should be supported by a revised data flow chart. The information should describe which individuals and organisations are involved in the project at each stage, where and by whom confidential patient information which be accessed, highlighting where this access will be undertaken with support under the Regulations. Clarification was also required around when patient data would be transferred between organisations and highlighting where this would involve the transfer of confidential patient information.

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 Group agreed that further clarity around the exit strategy from support under the Regulations was needed. The information currently provided was unclear due to the terminology which had been used. The applicant would be asked to provide further information in this area.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The Group recognised that work had been undertaken with the Citizen's Senate as part of the design phase of the project; however, the information which had been provided to feedback the outcomes of this interaction was limited. It was agreed that further detail would be requested around the activity which had been undertaken in this area, together with an overview of how patients and the public will be involved in the dissemination of research findings, as was detailed within the application form.

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 agreed that the poster which had been provided to facilitate a communications strategy required revision as it did not adequately describe the project. The document did not provide a clear overview of what the research involved, what patient data would be accessed and why. It was also commented that the objection mechanism should be operated by a local site PI rather than the student investigator for the project. Further information was also required to explain how the objection mechanism would be operated for the study as it was suggested that it may be necessary to display the notification materials with a lead-in time ahead of data extraction to enable a meaningful period of objection to be allowed.

The applicant would be required to provide further detail and revised documentation. It was recommended that consideration be given to the patient population which would be included in the study to ensure that any information materials were appropriate and accessible to this cohort.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. Assurance is currently provided against Version 14.1, 2017/18, of the IG Toolkit. Confirmation of the research sites involved in the project was required. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website for every organisation where confidential patient information will be accessed or processed with support under the Regulations.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. A copy of the REC favourable opinion would be required prior to any recommendation of support coming into effect.

Data Protection Act 1998 Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the Data Protection Act (DPA) 1998. Applicants must therefore demonstrate thorough the application that it is consistent with the DPA. Members acknowledged that the response provided in relation to the first DPA principle did not adequately describe how the data processing would be fair and lawful. Confirmation is required around the conditions within schedule 2 and 3 which have been met to show compliance against this principle. Additional information is also required around how patients and the public will be informed of the data processing.

Other Points

The Group noted that study data would be stored on an encrypted pen tool and concerns were raised around the security of this device. It was acknowledged that clarification had been requested around the status of the data which would be extracted from records and whether this would include confidential patient information. It was recommended that the applicant seek clarification that the use of such a storage tool was in line with the University's IG security policy.

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.

Request for Further Information (Summary)

The below list provides a high-level overview of the additional information which is required; however, reference should be made to the summary of the CAG consideration detailed above for further information.

1. Provide a clear overview of the elements within the application activity which require a recommendation of support under the Regulations to legitimise the data processing.
2. Consider the detail provided at Q56 around the classes of support which are required under the Regulations to support the application activity.
3. Clarify how the retrospective patient cohort will be established. This should confirm who is involved at each stage of the process and whether these individuals are members of the direct care team. The inclusion dates for the patient cohort should also be provided.

4. Confirm exactly which items of confidential patient information are required to facilitate the project and provide a clear justification for each item.
5. Provide a clear overview of the data flows within the project. This should explain which individuals and organisations are involved at each stage of the project and whether these individuals are considered part of the direct care team. Clarification is required around where data is transferring between organisations and whether this includes confidential patient information. This information should be supplemented by a revised data flow chart which depicts this information.
6. The exit strategy for the project requires clarification. Reference should be made to the ICO Code of Practice on Anonymisation to ensure accurate terminology is used to describe the status of data which has been extracted from patient's records.
7. Provide further information around the engagement activity which has been undertaken with the Citizen's Senate to date and explain how this group will be involved in the dissemination of the research findings.
8. Submit a revised patient information poster to address the issues referenced by the CAG.
9. Provide further detail around how the dissenting mechanism for the project will be operated to ensure a meaningful period of objection can be provided.
10. Confirm the research sites which will be participating in the study and provide details of the organisational code to enable assurance against the NHS IG Toolkit to be checked.
11. Further information is required to show compliance against the first principle of the Data Protection Act 1998 (Q57 of the application form).
12. It is recommended that clarification is sought from the relevant department at the University to confirm that the use of a pen tool is in line with the IG Security Policy.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee. **(Pending).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Pending).**

c. 18/CAG/0062 – Evaluation of antimicrobial prophylaxis after Manchester Arena bombing

Context

Purpose of Application

This application from Public Health England sets out the purpose of medical research to evaluate the effectiveness of the antimicrobial prophylaxis guidance, which was put in place following the Manchester Arena Bombing, to prevent wound infection in those injured. The primary research outcome is to determine rates of secondary wound infection in patients injured in the Manchester Arena bombing and who received antibiotic prophylaxis compliant with the antimicrobial policy.

Patients will be identified from records held by Greater Manchester Health Protection Team and Health Protection Scotland. Supplementary information will be requested from the eight hospital Trusts which initially treated patients, the patient's GPs and the Public Health England Second Generation Surveillance System, for those patients with documented wound infection.

Lists of the patient cohort are held by Greater Manchester Health Protection Team and Health Protection Scotland. The CAG remit extends to the list held by the team in Manchester only – the applicants will need to make a separate application to the Public Benefit and Privacy Panel for Health and Social Care to establish a legal basis to access the Scottish data.

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

Confidential Patient Information Requested

Cohort

- The 148 patients who were injured in the Manchester Arena Bombing.

The below confidential patient information will be extracted from the list held by Public Health England, and will be used to facilitate linkage in order to collate wider clinical information from hospital Trusts, GPs and the Public Health England Second Generation Surveillance System.

- Name – linkage,
- NHS number – linkage,
- GP Registration – linkage,
- Date of birth – linkage.

The following additional clinical information will be collated:

- Incidence of wound infection,
- Relevant antibiotic prescribing,
- Results of relevant wound swabs,
- Results of relevant stool samples.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured the application defined an appropriate medical purpose through medical research. Members discussed the sensitivities of the proposed research topic and patient cohort for inclusion in the project. This was balanced by consideration of the potential benefits for future patients should another incidence as this happen. The Group agreed the importance of gaining understanding to improve the care which could be provided in future established a public interest in this project progressing.

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 discussed the feasibility of consent for the patient cohort. The applicants had stated that, due to the context in which these patients received their injuries and the ongoing psychological distress which they are experiencing, contacting them for the purposes of research consent was not considered feasible. Members acknowledged that there were sensitivities involved in contacting this patient population; however, it was commented that the rationale which had been provided to support consent was not feasible could also be used to justify why this specific patient group should be given the opportunity to consent to the use of the data for the research purposes. The Group suggested that presuming that patients would find an approach about the research study too distressing could be quite paternalistic.

The CAG agreed that the current submission did not provide sufficient information to justify why consent was not feasible for this particular project. It was agreed that a recommendation against the project would be deferred pending additional information from the applicants in this area.

- Use of anonymised/pseudonymised data

It was recognised that confidential patient information was required to link patient information from a number of sources, which could not otherwise be achieved.

Justification of identifiers

The Group was assured that the items of confidential patient information which were requested were appropriate and proportionate to achieve the application activity.

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 had explained that it was anticipated that the linkage would be completed within three months of the project receiving all necessary regulatory approvals. At this stage, the applicants advised that all confidential patient information would be deleted from the dataset which would be used for analysis. The applicants stated that this anonymised dataset would be retained for 10 years.

The Group considered these proposals and it was discussed whether, due to the high-profile nature of the patient cohort which was included within the study; the resulting dataset would ever be truly anonymous. The applicants would be asked to consider whether they would need to extend the support under the Regulations to cover the retention of this dataset. If it was determined that this was not necessary, the applicants would be required to provide details of an assessment in line with the Information Commissioner's Office (ICO) Code of Practice on Anonymisation, to justify how these requirements were met.

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 provided an overview of interaction which had been undertaken and was proposed in future with the Manchester Arena Recovery Group. This was a multi-agency group which had been established to assist all aspects of the victims' recovery. It was acknowledged that whilst relevant third-sector organisations were represented within this group, the group comprised of various professional members. There did not appear to be any patient or service user involvement in the group. Members agreed that feedback from the future presentation session with this group would be required for consideration as it was recognised that the professionals involved in the care of these individuals would be able to provide an important viewpoint in relation to the study.

The CAG agreed that patient and public engagement was a key aspect for this application to ensure that a relevant group were supportive of the application activity proceeding without seeking the consent of the patients. Whilst it was acknowledged that this was a particularly sensitive area with a restricted scope in terms of appropriate engagement groups, Members suggested that there were a number of support groups which could provide an appropriate audience for discussion. It was also suggested that a support group for the victims of a similar attack may also provide a relevant viewpoint around the use of confidential patient information without consent for these purposes.

The Group agreed that further work would need to be undertaken in this area in order to explore the acceptability of the project proceeding without patient consent with a relevant audience. The outcomes of this activity should to be used to provide a stronger informed argument to support the applicant's rationale that consent is not feasible for this project.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right 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 was unclear whether the proposed notification strategy was adequate, as this passed the responsibility to inform the patients about the project to their GPs. It was commented that that the GP may not see the patient until after the data linkage has been undertaken, which would prevent any individual the option to raise an objection. The Group agreed that further work was required in this area to revise the patient notifications strategy, to ensure that if the GP was to provide the information, there was a lead-in time to allow for meaningful objection. It was also commented that a copy of the information leaflet would need to be provided for review.

Members further commented that the GP practices would have a record of any previous dissent raised by the patient in relation to the use of their confidential patient information for research purposes. The applicants would be required to include a system to check for any historic dissent.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed scores for Public Health England had been published in respect of version 14.1 (2017/18) of the toolkit; however, these self-assessments had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. Clarification of this review would be required prior to any recommendation of 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. Members agreed that the study presented some key ethical issues and as such, requested sight of the REC favourable opinion as part of any revised application.

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 following information should be provided to allow the CAG to continue their consideration of the application. Please refer to the summary of the CAG consideration above for further detail in relation to the below points.

The resubmission would require a detailed covering letter addressing the below points, together with a revised CAG application form and any additional supplementary documentation.

1. Further justification is required to support the argument that consent was not feasible for the project. This should be informed by meaningful engagement with an appropriate patient and public population.
2. Provide feedback from the presentation which is scheduled with the Manchester Arena Recovery Group.
3. Further work should be undertaken to improve the patient communications strategy. An overview of the revised strategy would be required, together with a copy of the information leaflet which will be used to facilitate this.
4. An overview of how an objection mechanism will be operated for the project is required, together with confirmation that GPs will be asked to check their records for evidence of historic dissent for the use of patient data for research purposes.
5. An assessment should be undertaken around whether the resulting dataset would be classified as anonymised, with reference to the ICO Code of Practice on Anonymisation. Consideration should also

be given as to whether the duration of support under the Regulations should be extended to cover the retention of this dataset.

6. Favourable opinion from a Research Ethics Committee should be provided for information.
7. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.

6. MINUTES OF THE MEETING HELD ON 08 MARCH 2018

The minutes of the meeting held on the 08 March 2018 were agreed as an accurate record of proceedings with no revisions.

7. CAG CHAIR REPORT

The CAG Chair report was received and noted by Members present.

8. ANY OTHER BUSINESS

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