Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

06 December 2018 at Skipton House, SE1 6LH

Present:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Dr Tony Calland MBE	Yes	Chair
Dr Patrick Coyle	Yes	Vice Chair
Professor Barry Evans	Yes	
Mr David Evans	Yes	
Dr Liliane Field	Yes	
Mr Anthony Kane	Yes	Lay Member
Dr Rachel Knowles	Yes	
Dr Simon Kolstoe	Yes	
Mr Andrew Melville	Yes	Lay Member
Mrs Diana Robbins	Yes	Lay Member
Ms Clare Sanderson	Yes	Alternate Vice-Chair
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Ms Amanda Hunn	HRA Joint Head of Policy
Miss Kathryn Murray	Senior Confidentiality Advisor
Ms Juliet Tizzard (Agenda Item 3.b. only)	HRA Director of Policy

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

The Chair welcomed Ms Juliet Tizzard, HRA Director of Policy, to the Committee meeting. Ms Tizzard was attending to observe the CAG to gain a greater understanding of its business.

It was noted that Ms Amanda Hunn, HRA Joint Head of Policy, was attending in capacity as nominated decision-maker for the Health Research Authority.

There were no apologies for absence reported.

The following declarations of interest were noted in respect of application 18/CAG/0196 (agenda item 3.b):

- Dr Willliam Bernal, CAG Member, is named on the application,
- Dr Murat Soncul, Alternate Vice-Chair, is Head of Information Governance at South London and Maudsley NHS Foundation Trust. SLaM's CRIS system is cited as precedent in the application,

2. APPROVAL DECISIONS

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 04 October 2018 meeting applications.

Health Research Authority Decisions

The HRA agreed with the advice provided by the CAG in relation to the 04 October 2018 meeting applications.

3. NEW APPLICATIONS – Research

a. 18/CAG/0194 – Risk assessment tool for self-harm in prisoners

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to develop a tool that will identify the risk of repeat self-harm amongst prisoners within three months post ACCT closure. Assessment, Care in Custody and Teamwork (ACCT), is a risk management plan, which is used to collect important information for prisoners considered at risk of self-harm and suicide, to assist in reducing self-harm and suicide in prisons.

The proposed study has three elements, for the CAG is only being asked to consider the initial part in relation to the development of the tool for which routinely collected data from prison healthcare records and ACCT documentation will be used to create a statistical model to predict repeat self-harm. The second phase of the study will be a qualitative phase working with staff and prisoners on a consented basis and the third phase will involve testing the tool in a cohort of prisoners at the end of their ACCTs.

The cohort to be included within the first phase of the study will be identified from a dataset which was created in an historical study. This original dataset contains 14,111 ACCT reviews opened between 2004 and 2017 in four prisons at the North of England [HMP NewHall (females), HMP Wealstun, HMP Hull and HMP Leeds]. The dataset contains pseudonymised prison number, date the ACCT was opened and closed, the location where it was opened, reason for opening and closing the ACCT, and post-closure review date.

The applicant is seeking support under the Regulations to access the wider clinical records of a sub-cohort of 1,000 patients enrolled in this previous study. The applicant will reverse the pseudonymisation process in order to access the individual prison ID numbers of patients, to enable access to the wider patient records held within the medical record system, SystmOne, which is a known clinical records system.

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

Confidential patient information requested

Cohort

Male and female adult prisoners (age 18 years old and above) that were on an ACCT following a self-harm episode (including threats of self-harm) between 2004 and 2017 in four prisons at the North of England [HMP NewHall (females), HMP Wealstun, HMP Hull and HMP Leeds, Prison categories (A to C)]. 1000 patient records would be accessed in order to establish the cohort of 750 to be included in phase one of the study.

The only item of confidential patient information required is Prison ID – the applicant has clarified that this identifier is used within the clinical records system, SystmOne, to identify individual patients.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. The aim of the project was to devise a tool to assist in the reduction of self-harm amongst the prison population, which Members agreed was within the public interest.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. The application stated that specific ethical approval was not being sought until the later stages of the project. In response to queries raised ahead of the CAG meeting, the applicant had stated that the ethical approval which was in place for the historic project, which created the database from which the proposed patient population would be identified, extended to the proposed activity. Copies of two favourable ethical opinions dating back to 2014 were provided; however, the named Chief Investigator on these proposals was a co-applicant on the application submitted to the CAG, not the main applicant. It was unclear how either of these historic ethical opinions extended to the proposed activity, noting that the CAG application had been submitted by a different applicant and applying organisation.

Members were unclear from the information provided whether there was a favourable ethical opinion in place for the first phase of the proposed research study, for which the applicant was seeking support under the Regulations. Specifically, confirmation is required that there is a current ethical opinion in place to cover the re-identification of the historic patient cohort and subsequent additional access to confidential patient information at the HMP York site to extract supplementary clinical information. The Group agreed that it was unable to provide a recommendation for the application until this issue was resolved as assurance was required that the appropriate and necessary approvals were in place.

Organisational Involvement

The Group commented that there was a lack of clarity around the organisational involvement within the proposal. It was noted that within the application, the University of York and HMP York appear to have been referenced interchangeably, and the relationship between the two institutions was unclear. Members agreed that the revised application should provide a clear overview of the relationship between the two

organisations. Clarity should also be provided around which organisation would be undertaking which activities within the project.

Scope of Support

The remit of the CAG is defined in section 251 of the NHS Act 2006 and its Regulations. Information that falls within the scope of Regulation 5 of the COPI Regulations is set out in the NHS Act 2006 and states it must firstly be 'patient information', which is defined at s251(10) and then 'confidential patient information' which is defined at s251(11). The Group noted that some of the data items cited within the application form clearly would not fall within the scope of these legal definitions and for these, support could not be provided. Employment and educational data, together with information related to the individual's offence were cited as examples from the dataset described which would not fall within the definition of confidential patient information. Members agreed that clarification was required from the applicant around all data items which were required for the purposes of the analysis and the source of this data, to provide a clear overview of what would fall within the scope of these legal definitions.

Cohort

The applicant had stated that access to 1,000 patient records was required to enable the 750 patients which were eligible for inclusion to be identified. It was explained that the first 1,000 patients would be selected for inclusion in the trial and Members were unclear how this was classified. The assessment of the scientific rigour and statistical elements of a proposal was within the remit of the REC. The Group stated that the outcome of the REC review would be required to provide assurance in this area. The CAG was unclear from the information provided within the application form why there would be surplus of 250 patients who were not suitable to be included in the trial. It was agreed that clarification would be required from the applicant in relation to this point.

Practicable alternatives

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

- Feasibility of consent

The CAG was assured by the applicant's rationale to support why it was not feasible to seek consent for the project. It was recognised that the historic cohort who would be included was sizeable and as a past prison cohort, was likely to be mobile. It was further noted that, as the study focus was on prisoners with a history of self-harm, it was likely that a proportion of the cohort would be deceased.

- Use of anonymised/pseudonymised data

Access to confidential patient information was required in order to facilitate linkage with wider records, to enable clinical information required for analysis to be extracted.

Justification of identifiers

The applicant had stated that prison ID alone would be required to access the wider clinical records. It was identified that prison ID was used within the SystmOne medical records system in prison, in place of NHS number. The Group raised no queries in this area as it was recognised that patient identifiers had been kept to a minimum.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The applicant had provided information around some activity in this area which had been

carried out with the families of prisoners; however, it did not appear that any direct activity had been undertaken with prisoners, past or present, around the use of confidential patient information for the purposes as set out in the application.

Members recognised the challenges around arranging involvement and engagement activities with current prisoners. However, it was commented that there was likely to be third sector organisations which provided support to ex-offenders which could facilitate activity in this area. The Group agreed that further activity was required in this area to seek the views of the appropriate patient population around the use of confidential patient information as described within the application. Feedback from this activity would be required to support the application. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, or whether further actions were necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and the Data Protection Act 2018.

The applicant had stated that the study would be promoted via a monthly prison publication, Inside Times, to raise the profile of study within the existing prison population. Objections could be raised via the Safety Custody Officer for those individuals who did not want their data to be used in the proposed study. Members acknowledged the difficulties in operating a communication mechanism for those patients who are still prisoners. The Group was satisfied that the proposed strategy was proportionate; however, it was agreed that the sight of the text would be required as part of any revised application for consideration.

The Group agreed that further work was required in this area to establishment a communications strategy for those individuals who were prisoners at the time of the initial study, but had subsequently been released from prison. The applicant would also be required to operate a dissenting mechanism for this sub-cohort. Members agreed that any revised application would need to address this area, explaining how and where the project would be promoted, together with copies of any materials to support this communication strategy, and an overview of how dissent can be raised. It was suggested that the patient and public engagement activity may help inform this strategy.

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 understood that patient records would be accessed at HMP York. However, in response to queries, the applicant had provided the data protection registration for the University of York, stating that this was the only organisation which would access and process confidential patient information. It appeared from this response that the requirements to provide security assurance were not clearly understood.

Security assurance is required for each organisation which would be processing confidential patient information with support under the Regulations. Where confidential patient information is being accessed on site, security assurance would be required for the site where the data is accessed, not the employing organisation of the individuals who are undertaking the data access.

Security assurance is provided by the NHS Digital review of an organisation's IG Toolkit submission. Assurance is currently provided against Version 14.1, 2017/18 of the toolkit. The Group agreed that the revised application should clearly outline the sites where confidential patient information would be accessed and provide confirmation of the corresponding IG Toolkit organisational code to enable security assurance to be confirmed.

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.

Request for further information (Summary)

1. Confirmation of the status of the NHS REC review for the proposal is required, together with clarification around why it is understood that the historic approval for a separate proposal would extend to this study.

2. Clarification is required around the roles which would be fulfilled by each of the organisations named in the application. Particular clarity is required around the relationship between the University of York and the HMP York.

3. Further information is required to understand how the cohort of patients would be identified and assessed as eligible to be included in the study.

4. Provide a detailed overview of each item would be included in the analysis dataset together with the source of the information, in order to clearly define which items would fall within the legal definition of confidential patient information.

5. Further patient and public involvement and engagement activity should be undertaken in order to seek the views of an appropriate group, around the use of confidential patient information for the application purposes.

6. A copy of the text to be included in the 'Inside Times' publication should be provided for review.

7. A wider communications strategy should be devised to raise the profile of the study amongst past prisoners who were now released and offer a means to dissent to the use of their data. Copies of any documentation to facilitate this should be provided, together with an overview of how the objection mechanism would be facilitated.

8. Clarify where confidential patient information would be process and provide confirmation of the organisation's NHS IG Toolkit reference code to enable security assurances to be checked.

b. 18/CAG/0196 – Health data research of Kings College Hospital digital health records

Purpose of application

This application from King's College Hospital NHS Foundation Trust set out the purpose of medical research through the establishment of a research database, which will be called the King's Electronic Records Research Interface (KERRI) system, derived from the electronic patient records held at the Trust. A locally developed information retrieval system ('CogStack') would be used to process data from within King's College Hospital NHS Foundation Trust electronic patient records into a de-identified database in a searchable format for the purposes of health data research. The CogStack technology pools data from many internal sources including patient appointment systems, pathology results, electronic patient health records, imaging and diagnostics and letters and scanned documents. This would mirror the live records system at a 15 minute delay and pass it into an algorithmic pipeline. The de-identification pipeline generates a de-identified version of individual health records removing identifiers as well 'weakening' data that carries a risk of re-identification. Data stored within the KERRI research database would present episodes of care and not a complete patient record.

The application had been submitted for support to avoid a breach of the common law duty of confidentiality. The reason for the submission was that the applicant stated they intended to use information originally collected for direct care purposes for the secondary purpose of research without obtaining consent. The applicant presented the position that patients provide their confidential health information for the purpose of

allowing personalised care and have the expectation that the data is not being used for alternative purposes without consent. Support was sought to use this information for a purpose different from that under which it had been collected.

The KERRI research database and governance has elements that have been modelled on the CRIS (Clinical Record Interactive Search) database which was established by South London and Maudsley NHS Foundation Trust in 2011. The CRIS database did not obtain support under the Regulations for its creation due to the data flows and de-identification techniques in place; however, applications were made for subsequent linkages with wider datasets and supported.

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

Confidential patient information requested

Cohort

The cohort will consist of all patients treated at King's College Hospital NHS Foundation Trust from 01 March 1999. It is estimated that the retrospective element would include the provision of care to approximately 1.38 million patients. Patient treated prospectively at the Trust would also be included.

Patient records will be processed by the Cogstack system on an episodic basis in order to create a de-identified database to be used for research purposes. Complete identifiers would be redacted from the patient records.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members were extremely supportive of the principles of the project and recognised there was potential for significant benefits that could arise from appropriate use of the proposed database. There was no question from CAG that there was a clear public interest in this activity proceeding.

Consideration of need for support

Members were clear that support could only be advised where a breach of the common law duty of confidentiality would be involved. In this instance, the Trust as controller was legitimately in possession of the relevant information obtained through the provision of direct care. No further data processors would be involved. The CAG raised the question whether in this specific circumstance the Trust as controller, with no further onwards disclosure in an identifiable format to any other parties, could legitimately use the information for a secondary, non-care purpose, without involving a breach of confidentiality, and whether support was in fact necessary. Members noted that this very question had been raised by CAG in early October, and the question was currently undergoing active consideration by the National Data Guardian and Department for Health and Social Care; CAG was pending the outcome of these evolving discussions. In light of the fact that there was not a clear legal position in place, and as CAG is not constituted to take legal decisions, members noted that they would be unable to provide a recommendation until it was clear whether support would be necessary to avoid a breach of confidentiality. This clarity was currently dependent on progression by the Department of Health and Social Care.

Broader elements of the application

Members accepted that the CAG was currently unable to provide a recommendation as to whether support could be recommended due to broader national issues requiring clarity. However, notwithstanding this outstanding fundamental point, members considered the application as a whole and agreed it would be helpful to raise points for applicant to review to inform a revised submission if this was ultimately deemed to be necessary.

The following sets out comments for the applicant to review, however, please note that these are advisory only and should only be formally be responded to the CAG when a clear situation as to the need for support is reached. Even if a submission to the CAG is ultimately not deemed to be necessary, members agreed these would be helpful to the activity in terms of refining and clarifying some elements. It has been agreed that the CAG will contact the applicant directly when a national position is reached so these comments should be considered in the interim without being constrained by the pending national position.

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 project intended to process historic records relating to approximately 1.38 million patients. The CAG was assured that seeking consent for this historic cohort was not feasible due to these large numbers. It was also intended to include the records of all prospective patients treated at King's College Hospital NHS Foundation Trust within the database. Members recognised that this was a significant undertaking for which seeking individual patient consent would not be feasible.

- Use of anonymised/pseudonymised data

The application stated that the resulting database would be de-identified and support was being sought for the creation and update of this de-identified information for secondary research purposes. However, at Q12-2 of the application form, it was stated that a project-specific identifier would be constructed for every record as it passed into the KERRI database, using an encryption algorithm based on the hospital ID. It was commented that as the KERRI identifier was not randomly allocated to records, it was unclear whether there was potential for the encryption to be reversed.

Accepting that data protection compliance does not lie directly within the remit of the CAG, members noted that the issue as to the risk of re-identification was a critical one. This was deemed so firstly in terms of whether support may be appropriate if there is a reasonable risk of re-identification and extent of genuine de-identification. The second reason is that Recital 26 of the GDPR sets out the framework when assessing when information is and is not considered to be personal data.

The resulting KERRI database was described in the application form as de-identified and it was stated at question seven that once this de-identification process had taken place, the anonymous data would no longer be considered to be personal data. Members considered the dataset which would be held within the KERRI database, including the example provided of how redacted free text information would be incorporated.

Free text information

Members noted that free text information typically holds a richness of unstructured information and it can be particularly difficult to be assured that free text information has been appropriately de-identified without manual intervention. It was queried whether there was a high risk of re-identification due to the richness of information which would be held within the database, which would include gender and date of death. For example, it was recognised that whilst direct patient identifiers would be redacted from free text information, patient title would remain. It was queried whether the risk of re-identification would increase with social context, which was particularly relevant if the patient's title was honorific. The Group agreed that further information was required from the applicant to explain how they would assure themselves that the resulting database was truly de-identified and anonymous. This point was particularly relevant to free-text information and the applicant's confidence in the Cogstack software to fully redact all identifying patient

information. It was also agreed that further information was required around how the risk of re-identification had been assessed by the applicant to assure themselves that all risks of re-identification had been genuinely removed. .

Whilst it is understood that the de-identification process would be automated, it was noted at question 12 of the application that there would be a rolling audit of data to ensure the success. It was unclear whether this process would involve manual auditing against the source data and thus review of confidential patient information by an individual. Clarification was required around this point. In conclusion, the Group advised that there should be a re-evaluation in light of the member comments around re-identification risks of free text information. Any doubt in this area, following an internal review, may mean that the ongoing retention and use of data for research purposes may eventually require a recommendation of support under the Regulations, if risks are not appropriately minimised.

KERRI Data Access Committee

The Group agreed that based upon the information submitted that they were not entirely clear how applications to access the KERRI database would be made and considered, what protocols were in place to assess the requests and what criteria would need to be achieved before access was granted. It was noted at Q12-2 of the application form that proposals which had a moderate-to-high risk of re-identification would be asked to seek project-specific approvals. Members agreed that further information was required to understand how the risk of re-identification would be assessed and by whom and what specific approvals an applicant would be required to seek. The CAG considered whether the KERRI access committee had plans to publish details of any future disclosures in order to meet transparency requirements. The applicant was asked to consider how information would be made publicly available on the process and any disclosures that may subsequently take place.

Further information was also requested around how data would be released and whether there would be any specific assessment undertaken to provide assurance that the dataset was anonymised prior to release. Confirmation was also required that appropriate controls were established to prevent applicants from using the data for any wider purposes than those set out within the access application.

The CAG considered the documentation which had been provided to support the application process to access the KERRI database. Within the CAG application form, it was stated at Q18 that wider NHS, governmental and not for profit organisations would not be excluded from applying to use the database. Members commented that the KERRI project application form and the language used within this, seemed that it was designed for only internal Trust use, therefore there appeared to be an inconsistency in the paperwork submitted. Revised documentation may be required if access to the KERRI database was to be more widely considered. For example, at present, the documentation does not require the applicant to identify the sponsoring institution and/or the employer who would require and enforce the necessary duty of confidence.

Members were also unclear whether, in terms of the management of the KERRI database, audit trails would be established to log access and activity within the database to provide further security assurances. Members advised that further clarity would be required around the general management of the database to ensure that appropriate and transparent governance arrangements were in place to monitor and manage access.

Handling of poor clinical practice

The Group recognised that there was potential for the database to identify poor clinical practices by highlighting trends in adverse events and outcomes. It was recognised that, by the proposed methodology of the database, an individual patient or practitioner could not be identified by the information retained in the database; however, it was unclear whether there was any wider system in place to manage these type of issues if these presented. The applicant should considering further necessary reassurances in this area, explaining what mechanism was in place to manage this circumstance.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The applicant had provided a report around the activity which had been undertaken to date in this area. Two focus groups had been carried out in late 2017, involving a total of 13 patients across 10 specialisms. It was noted that the aims of the engagement sessions were broader than the KERRI project as there was discussion around consent for research contact initiatives, which as a de-identified database, the KERRI project would not facilitate, however members appreciated that PPI had been undertaken. .

The Group recognised that the activity which had been undertaken to date was supportive and appropriate to the proposal. However, Members were unclear from the information presented whether those involved in the engagement activity were representative of the demographics of the patient population served by the Trust. It was also commented that, given the scope of the proposal, which would include the use of sensitive patient records pertaining to sexual health and HIV services as examples, it would be important to understand patient views around the use of this type of data without consent. The Trust, as referenced within the application, had active engagement initiatives with its service users via patient and public involvement groups, volunteer lists and the patient membership scheme. It was also recognised that the applicant had planned further patient and public engagement activity in order to develop patient-facing information materials to support the communications strategy. Members agreed that this planned activity and the established networks should be utilised to seek more specific engagement around the scope of the KERRI project with a wider patient group, with particular focus on the use of data from areas of care which are considered more sensitive.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and a mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation (GDPR) and the Data Protection Act (DPA) 2018.

A communications strategy had been devised to support the KERRI database, involving information leaflets and posters for patients and staff. These physical documents would be supplemented by wider communication mechanisms including a presentation, video/animation, online content (internet, intranet, and social media) and wider editorial and e-marketing content. Information about the database and opt-out would be translated into key languages appropriate to the demographics of the Trust locality. The Group was assured that the established communication plan was an appropriate approach to effectively promote the prospective data collection into the KERRI database.

Members were unclear how the proposed communication strategy would promote the inclusion of the retrospective patient cohort within the KERRI database. It was recognised that the supporting documentation provided in this area was in draft format and may address this element in its finalised format; however, the Group was not assured on the basis of the presented information that sufficient measures had been put in place to inform the retrospective cohort. The CAG was mindful of the limitations of informing this historic cohort; however, it was suggested that wider communications within the geographical locality served by the Trust may be helpful in raising awareness of the scope of the project and reaching historic patients. It was also noted that the Trust had a patient membership scheme which could also be used to facilitate wider communications. The applicant should therefore consider ways in which the communications strategy could be improved to ensure reasonable measures had been put in place to inform the historic patient cohort about the creation of the database. Members commented that the applicants would also need to address this point regardless to ensure the proposed activity was compliant with the fair processing requirements under GDPR, and pointed to current HRA guidance published on the implications of GDPR for research.

The Group considered how an opt-out mechanism would be operated for the database. It was understood from the information within the application that prospective data entry into the KERRI database would happen in real time, with a 15 minute delay behind the entry of information for direct care purposes. Members were unclear how this process would facilitate a meaningful dissenting mechanism for patients, as once the data had transferred into the KERRI environment, a patient could no longer be identified. This suggested that patients would have a limited time to raise an objection to the use of their data for research purposes, as this could not be applied retrospectively. The CAG agreed that further information was required in this area to understand how the opt-out mechanism provided would work in practice together with assurance that patients were being provided a meaningful opportunity to raise an objection. It was noted that the right to raise an objection was a key finding in the report provided from the patient engagement sessions and was a requirement in order to be compliant with the fair processing requirements under GDPR.

Confidentiality Advisory Group advice conclusion

In line with the considerations above the CAG agreed, while supportive in principle of providing a positive recommendation of support, that it required external confirmation as described above that the scope of support being requested was within remit to consider. This is because the CAG cannot recommend support where it is not necessary. The pending position on this issue is expected to address this point however it was appreciated that this was not within the applicant's remit to influence and the CAG itself is dependent upon others before a satisfactory conclusion can be reached.

As there is potential for support to be a future option, while acknowledging that the points and clarifications the CAG identified may help direct thinking as to whether or not support is ultimately appropriate. The CAG has deferred providing a recommendation and has provided instead points for the applicant to consider as the majority link to issues important when considering establishing a research database. The CAG is awaiting the outcome of the broader policy position, but has agreed to inform the applicant directly when this position is clarified, accepting that actions rest in other organisational remits at present so is unable to provide a timescale as to when this may be forthcoming.

Points for the applicant to consider

The following points provide a summary of the points raised by the CAG, which the applicant should consider as part of building robust governance arrangements and minimisation of risks of re-identification, while a clear position as to whether support is necessary in these circumstances, is pending resolution.

1. The applicant should consider how they have assured themselves that the resulting database would be truly anonymised. This should include:

    a. The use of a project-specific ID which is generated using an algorithm based on Hospital ID, rather than a random number, Assessing whether the KERRI database identifier, generated using an algorithm based on hospital ID, carried any risk of re-identification, which could be reduced by assigning a randomly generated ID,
    b. Articulating the level of confidence in the CogStack system to completely and accurately redact confidential patient information from free-text information, which appears to be a key risk element,
    c. The risk of re-identification from the richness of the dataset included within the database and how this has been assessed, accounting for the inclusion of patient title, gender and date of death within the dataset,
    d. Whether the 12-month rolling audit of the de-identification process would involve human intervention which may lead to inadvertent disclosure,
    e. It is possible that the outcome for these considerations may set out a clearer need for support, in the event the database is not considered fully anonymised..

2. Further consideration should take place around the KERRI Database Access Committee to address the following points:

a. A clear overview of the application process to explain how assessments would be made, what protocols were in place to support this assessment and the criteria which would need to be achieved by an applicant in order for access to be granted,
b. How applications would be assessed for risks of re-identification, how these risks would be classified, against what standards, and what approvals an applicant would be requested to seek for medium to high risk proposals,
c. What transparency arrangements would be put in place around the work of the Access Committee and how this would be made publicly available to support good transparency,
d. Clarify how data would be released to, or accessed by, successful applicants and whether any assurance checks would be carried out to ensure the data had been fully de-identified,
e. Confirm what controls would be in place to ensure that the data was only used for the specific purposes set out in the research application,
f. Provide further detail around how applications from outside the Trust would be managed,
g. Confirm what audit trails and security protocols would be put in place to monitor access and activity within the database.

3. Assurance would be required that a protocol was in place to manage the identification of potential poor practice together with an overview of how this would be managed.

4. Further specific patient and public involvement and engagement activity should ideally be carried out:

    a. to seek the views of a wider group, which are consistent with the demographics of the locality served by the Trust,
    b. Specific focus should be given to seeking views around the use of data related to sensitive areas of medicine; feedback on the wider activity carried out in this area would be very helpful to strengthen the public interest in this activity proceeding,
    c. It was recognised that the activity previously undertaken may have covered these specific areas; however, the feedback report provided did not specifically address these points.

5. Patient Notification and dissenting mechanism:

    a. Further consideration should be given to the communications strategy for informing past patients about the establishment of the KERRI database,
    b. further consideration should be given around how patients would be provided the opportunity to object to the inclusion of their data within the KERRI database, together with confirmation of how any dissent would be respected,
    c. If the ultimate position is that an application should be made to the CAG, sight of the finalised public-facing information materials to support the communications strategy would be required.

c. 18/CAG/0198 – Mortality in MitraClip treated patients compared with standard care

Purpose of application

This application submitted by the Royal Brompton & Harefield NHS Foundation Trust on behalf of Harvey Walsh Ltd. set out the purpose of medical research which aims to understand the all-cause mortality and healthcare resource utilization (HCRU) in patients treated with MitraClip compared with those treated with standard medical therapy for moderate or severe mitral regurgitation at the Royal Brompton & Harefield NHS Foundation Trust between 2015 and 2017.

Mitral regurgitation is leakage of blood backward through the mitral valve in the heart each time the left ventricle contracts. MitraClip is a percutaneous edge to edge treatment for mitral regurgitation, addressing the leaflets of the valve. It has received a CE mark and has been implanted in more than 50,000 patients worldwide.

The study will involve identifying eligible patients from electronic records at Royal Brompton & Harefield NHS Foundation Trust. Confidential patient information will then be disclosed to NHS Digital to link the patient cohort with HES and ONS mortality information. NHS Digital will remove all patient identifiers from the linked dataset, prior to release to Harvey Walsh Ltd. for analysis. Data will be analysed retrospectively for the 12 months prior to the index date (defined as the date of MitraClip procedure or the date of first standard medical therapy received following MDT) to capture patient's prior clinical characteristics and HCRU, and for a period of 24 months post index (or until death if sooner) to collect post procedure data on HCRU and mortality.

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

Confidential patient information requested

Cohort

All patients who received percutaneous mitral valve repair with MitraClip at the Royal Brompton and Harefield NHS Trust during 2015 to 2017 and a matched cohort of patients declined for MitraClip on anatomical rather than clinical co-morbid grounds during 2015 to 2017. A sample of 130 patients will be included in this study; 90 patients treated with MitraClip and 40 patients treated with standard medical care.

Confidential patient information will be released from Royal Brompton & Harefield NHS Foundation Trust to NHS Digital to facilitate linkage with HES and ONS. The following items of confidential patient information are requested:

- NHS Number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Date and cause of death (month and year format) – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. It was explained that the purpose of the study was to gain an understanding of the impact of the MitraClip treatment in the real-world clinical setting. Members were unclear how this would be achieved when considering the limited patient sample which would be included in the study.

The Group understood that a national registry existed, which was maintained under the NICOR programme (National Institute for Cardiovascular Outcomes Research). The registry recorded information on all percutaneous mitral valve repair with MitraClip procedures performed in the UK since the introduction of the technique. As the registry included data on all patients within the UK, this presented a much larger patient cohort for analysis. On the basis of this existing registry, Members were not assured that the proposed activity was within the public interest. The CAG deferred recommendation on the application on this basis.

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.

- NICOR Registry

The Group agreed that the national registry maintained by NICOR, appeared to present a practicable alternative to seeking support under the Regulations for the proposed activity. Members were unclear

whether the registry would be able to provide the comparison cohort. However, it was agreed that the applicant would need to explore this option. If it was determined that the established national registry did not present a feasible practicable alternative, a strong justification would need to be provided to support this decision as part of any revised application.

- Feasibility of consent

The applicant had explained that, due to the poor prognosis for this patient population, it was likely that a significant proportion of the patient population would be deceased, or no longer under active follow-up with the Trust. Members were assured that, in the scope of the proposed activity, consent was not feasible on this basis.

- Use of anonymised/pseudonymised data

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

Justification of identifiers

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

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. It was cited that all items of confidential patient information would be destroyed by NHS Digital once the data linkage had been undertaken. Analysis would be carried out on a pseudonymised dataset.

Members considered the content of the analysis dataset. It was unclear whether any assessment of the risk of re-identification from the resulting analysis had been undertaken. It was queried whether inclusion of the date of the procedure was a potentially strong identifier, which could increase the risk of re-identifying the patient sample. The Group agreed that further assurance would be required in this area, should a resubmission be made.

Members also agreed that assurance would be required that Harvey Walsh Ltd., the third party organisation contracted to undertake study analysis, would only use the study data for the purposes specified in the application.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation as enacted by the Data Protection Act (DPA) 2018. Applicants must therefore demonstrate through the application that it is consistent with current data protection legislation.

It is a requirement that the applicant confirm which of the named organisations is acting as controller for the activity. The controller, under data protection legislation, is defined as the organisation which determined the purpose and manner in which data would be processed to achieve the project aims. Clarification had been sought in this this area as it was unclear from the information presented in the application what roles each named organisation would fulfil. A clear response had not been provided ahead of the application review.

Should a revised application be submitted, a clear statement around the roles of all named organisations would be required to support the application. This would include the role of the named Trust, Harvey Walsh Ltd and the device manufacturer, which was referenced within the protocol. Evidence would be required from each organisation to confirm it was signed up to fulfil the role cited. The revised application form would need to be authorised by the organisation acting as controller for the proposal.

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 project had been considered by a number of committees which had patient representation. It was further explained that the project had been discussed with Pumping Marvellous, a heart failure patient group. The feedback provided around the activity in this area was limited and it was unclear whether patient views around the use of confidential patient information for the study purposes had been sought.

The CAG agreed that further information would be required around the activity which had been carried out in this area within any resubmitted application. Confirmation that the use of confidential patient information had been explored with patients and the public, together with the feedback provided would be required. If the responses given were negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and the Data Protection Act 2018. It was explained that posters would be displayed within waiting rooms within the hospital Trust which would explain how patients could raise an objection to the use of their data within the study.

The Group commented that it was unlikely that the posters would be seen by the relevant patient population, as the applicant had stated the surviving patients in this group would be unlikely to be under active follow-up within the Trust. It was also noted that the document did not provided any contact details, should a patient wish to raise an objection.

Members advised that this principle should be considered and incorporated within any new submission, considering practical measures that could be taken, and highlighting any difficulties, in achieving a wider communications mechanism for the study.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed, while supportive in principle of recommending support, requested assurance that there was no other practicable alternative. Further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Request for further information

The following points would need to be addressed by the applicant, prior to submitting a further application to the CAG.

Practicable Alternatives

1. The applicant should explore the possibility of using the percutaneous mitral valve repair national registry maintained by NICOR as a practicable alternative to seeking support under the Regulations for the proposed activity. Contact should be made with the NICOR team to discuss the proposed study and explore whether the required data could be provided in an anonymised format direct from the registry database. If this proposal is *evidenced not to be* feasible, a revised application could be submitted to the CAG to seek support under the Regulations for this activity.

If submitting a revised application to the CAG, the applicant would be asked to consider the following points within the revised submission. A detailed covering letter should be provided which addressed the below points, together with a revised application form and wider supplementary documentation,

1. The applicant should resolve locally the organisational roles within the application and provide clear information around which organisation is acting as controller for the project. The roles of wider organisations referenced within the application should be confirmed and supported by evidence that each organisation has signed up to this role. A new application would need to be authorised by the relevant controller.

2. Provide further information to justify how the proposed activity was within the public interest.

3. Clarification is required around how the applicant had assured themselves that the risk of re-identification within the analysis dataset had been minimised.

4. Provide assurance that Harvey Walsh Ltd. would only use the analysis dataset for the purposes specified in the application and no wider activities.

5. Further information is required around the patient and public involvement and engagement activity which has been carried out. Provide details of how the use of confidential patient information within the study had been tested, together with feedback from those present. If the responses given are negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.

6. Provide consideration of opportunities to provide appropriate patient notification to the relevant cohort, provision of any relevant information to be provided to patients, and consideration of any difficulties to achieving this.

d. 18/CAG/0200 – Longitudinal Study of Pelvic Floor Dysfunction (ProLong20+)

Purpose of application

This application from the Glasgow Caledonian University set out the purpose of medical research which aims to follow-up the UK-based participants of the Pro-Long study, which originally recruited 8,000 women across England (Birmingham), Aberdeen (Scotland) and Dunedin (New Zealand) three months after giving birth, to study the effects of childbirth on pelvic floor dysfunction (urinary and faecal incontinence, pelvic organ prolapse and sexual dysfunction). The previous study showed a steady increase in the reporting of problems from the patient cohort up to 12 years post birth.

The proposed study will trace the previous participants, who are likely to be around the age of the menopause, when pelvic floor dysfunction is thought to be even more common and invite them to take part in a postal questionnaire and attend for a pelvic floor examination. The application has been made to the CAG to enable the patients to be traced via NHS Digital, prior to circulation of invitations, to enable mortality status to be checked via ONS and address details to be updated via the Patient Demographics Service. The application relates only to English patients – a separate application is being made to the Public Benefit and Patient Privacy Panel on Scotland. The applicants are also seeking to update records via linkage with NHS administrative datasets; however, this linkage would only be carried out for patients who provided consent to this data linkage.

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

Confidential patient information requested

Cohort

Women who previously consented to participate in the ProLong study. The CAG application extends to patients in England.

Confidential patient information will be released by the Glasgow Caledonian University to NHS Digital to facilitate linkage with ONS and PDS datasets. For patients found to be deceased, only fact of death would be reported and no updated address details provided. The following items of confidential patient information are required for the study purposes:

- ProLong Study ID – sample validation and return of linked data,
- Name – sample validation and linkage – updated by NHS Digital and returned to facilitate invitation process,
- NHS Number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Sex– sample validation and linkage,
- Postcode – sample validation and linkage,
- Current address and postcode – to facilitate invitation process,
- Mortality status – sample validation – fact of death only.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members recognised that the longitudinal follow-up of this established patient cohort was within the public interest, due to steady increase in pelvic floor dysfunction being reported within the cohort in previous follow-ups.

Practicable alternatives

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

- Feasibility of consent

The Group recognised that support under the Regulations was being sought to validate the existing patient cohort, through checking mortality status and updating contact details, via NHS Digital. Patients would be approached for consent following this validation activity. It was recognised that it was not feasible to seek prior consent for this activity and no issues were raised in this area.

Members agreed that the applicants should take advantage of this additional contact with the patient cohort to seek specific consent for further follow-up and the required prior sample validation via NHS Digital. This would prevent the requirement for subsequent applications to seek support under the Regulations for this activity. Revisions would be required to the patient information and consent materials to address this point.

- Use of anonymised/pseudonymised data

Confidential patient information is required to facilitate the linkage which would be carried out by NHS Digital, which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

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

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The study has an appointed Consumer Advisor who fulfils the role of lay advisor based on her previous experience as a patient. It was confirmed that this individual was supportive of the proposed activity and the processing of confidential patient information without consent.

Members were disappointed at the level of activity which had been undertaken in this area, as it was recognised that this was a well-established, longitudinal research study. It was acknowledged that the study involved an engaged patient cohort, evidenced by the high-level of response achieved at the previous follow-up. The Group agreed, on the basis of the engaged patient population, there would be no requirement for supplementary information in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and the Data Protection Act 2018. The applicant had established a communication mechanism through provision of information on linked websites around the study follow-up. A drafted privacy notice had been provided, together with confirmation that this would fulfil both fair processing requirements under the GDPR and patient notifications under the common law.

Members commented that patients were not currently being provided a clear means to raise a dissent prior to being invited to participate in the follow-up study. It was agreed that a patient should be able to object to disclosure and processing undertaken by NHS Digital. Further information would be required from the applicant to explain how this system would be operated.

It was recognised that the study focused on patients initially recruited from the Birmingham Women's Hospital. Whilst it was recognised that some patients may have relocated from this area, the Group suggested that wider communications could be achieved through the display of information within the gynaecology and urology clinics at this Trust site. This would also allow for an objection mechanism to be operated. Members agreed that the applicant would be asked to consider this wider communication mechanism and provide copies of any wider documentation to support this.

Confidentiality Advisory Group advice conclusion

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

Request for further information (Summary)

1. Confirm that the consenting process for the 12 year follow-up would include specific consent for any future follow-up. This should include specific consent for any tracing of validation activities to be carried out via wider NHS organisations prior to the approach for consent. Revised patient information and consent materials should be provided for information.

2. Consider providing wider patient notification materials within relevant outpatient clinics at Birmingham Women's NHS Foundation Trust, in order to raise the profile of the follow-up study more widely. Copies of any documentation used to facilitate these wider communications should be provided for review.

3. Confirm how patients would be able to object to the processing of confidential patient information prior to the formal approach for consent. Revise any patient-facing materials as necessary to include this objection mechanism and provide for review.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed**).
2. Confirmation of satisfactory security assurance from NHS Digital (**Confirmed – Glasgow Caledonian University has DSPT has been reviewed as standards met (equivalent of satisfactory reviewed grade on IGTK) and NHS Digital has a published satisfactory reviewed grade on V14.1 2017/18 of the IG Toolkit**)**.**

e. 18/CAG/0205 – Long-term survival after surgery. Version 1.4

Purpose of application

This application from Queen Mary University of London on behalf of Barts Health NHS Trust set out the purpose of medical research to follow-up patients who were enrolled in the International Surgical Outcomes Study (ISOS). ISOS was an international seven-day cohort study of adults undergoing in-patient elective surgery that provided detailed data describing post-operative complications and associated mortality.

Part of the planned analysis of ISOS was to follow up patients by linking to national datasets via confidential patient information to determine the long-term survival. ISOS completed patient recruitment, and closed, in 2014 and patient consent for linkage to national datasets to enable long term follow up of those recruited within England was obtained. NHS Digital has subsequently advised the applicant that the historic consent is no longer deemed to be valid for the purposes of linkage, which brought about the application to the CAG.

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

Confidential patient information requested

Cohort

Patients who consented to participate in the International Surgical Outcomes Study. The original study inclusion criteria was any patient aged over 18 undergoing elective surgery.

Confidential patient information will be released from Barts Health NHS Trust to NHS Digital to facilitate linkage with HES and ONS information. The following items of confidential patient information are required for the purposes specified:

- ISOS Study ID – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Sex – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Postcode – sample validation and linkage,
- Date of death – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the activity defined an appropriate medical purpose, which was medical research. Members were assured that the follow-up of patients to establish long-term survival following

elective surgery was within the public interest. The initial study was fully consented, which extended to the 12-month survival follow-up. The Group recognised that the one-year follow-up data would provide a dataset for comparison with the wider global study participants. Members were also assured that undertaking of longer study follow-up to three years was also within the public interest.

Background to Submission

The applicants had made a submission to the Data Access Request Service (DARS) team at NHS Digital in order to facilitate linkage with the datasets relevant for the study follow-up procedures. The applicant advised that, due to delays experienced in gaining approval for the follow-up data linkage, they now sought follow-up data for three years. The application was subsequently considered by the Independent Group Advising on the Release of Data (IGARD) at NHS Digital. The IGARD did not recommend the application for approval on the basis that there was discrepancy between how the data linkage was described between the protocol and the patient information materials. IGARD also queried the duration of follow-up data requested as the historic consent extended to one-year follow-up only. In subsequent correspondence with the DARS team, the applicant was advised to submit an application to the CAG to seek support under the Regulations for the application activity.

Practicable Alternatives – Assessment of Consent Materials

Members noted that the consent requirements under the General Data Protection Legislation (GDPR) placed a far higher threshold in relation to consent than that of the common law. In particular, Members considered the context of the study, the documentation, and the concept of 'reasonable expectations' of the participant and what would potentially be their expectations when providing the original consent. It was not clear to Members whether the assessment undertaken by NHS Digital had considered the consent materials in relation to 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 sheet and consent form as part of their consideration. Members reflected that in 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.

The Group took into account 'reasonable expectations' of the cohort which had provided consent informed by the study documentation considered. It was agreed that under the common law duty of confidentiality, the consent was valid for the 12-month follow-up, and processing of information for this specified purpose would not involve a breach of confidentiality. The following points were determined by the CAG to provide a sufficient legal basis, in relation to the common law duty of confidentiality, to legitimise the proposed data processing:

- The information sheet states: '*Patients will be followed up until they leave hospital. We will then follow your health status for one year using an NHS database called the Health and Social Care Information Centre (HSCIC)'.*

- The consent form includes the following consenting point: '*I give permission for these individuals to have these data. I consent to the research team at the UK Coordinating Centre to be sent and use information held by the NHS database, The Health and Social Care Information Centre (HSCIC), to keep in touch with me and follow up my health status'.*

In line with this, support under the Regulations could not be recommended for the data processing related to the 12-month follow-up, as an alternative legal basis was already in place, and processing of the specified information could proceed using the existing consent as the lawful basis to avoid any breach of the common law duty of confidentiality.

The Group agreed that the consenting materials did not provide sufficient legal basis, under the common law duty of confidentiality, to support the provision of data for the extended follow-up to years two and three. The CAG made this assessment as the information and consenting materials specifically referenced a 12-month follow-up duration. Members were assured of the wider public interest in undertaking an extended follow-up of the patient cohort. On this basis, the CAG was content to provide a recommendation of support under the Regulations to facilitate follow-up for the further two years.

Practicable alternatives

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

- Feasibility of consent

The applicant stated that it was not feasible to re-approach the patient cohort for consent as contact details were not retained to facilitate this process and it was recognised that a proportion of the cohort would be deceased. The Group was assured by the applicant's rationale and agreed that consent was not feasible for the project.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage with wider NHS administrative datasets by NHS Digital which could not be otherwise achieved.

Justification of identifiers

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

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and the Data Protection Act 2018.

The applicant had updated information on the study website to inform the patient cohort around the extended follow-up period, which also provided contact details to enable objection to be raised. The Group considered the content of the text and it was agreed that the content should be updated to explain that the extended follow-up was supported under the Regulations. It was also commented that the items of confidential patient information detailed on the website did not correspond with that included in the application to the CAG. Members agreed that the text should be checked for accuracy and a revised draft provided for consideration.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Revise the website text to provide a clear explanation that the extended follow-up is being carried out with support under the Regulations. The items of confidential patient information referenced in the text should be checked against those cited in the CAG application, to ensure these are fully referenced.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - NHS Digital and Barts Health NHS Foundation Trust have published satisfactory reviewed grade on V14.1. 2017/18**).

f. 18/CAG/0206 – Chemotherapy Dose Reductions in Palliative Lung Cancer V1.0

Purpose of application

This application from the University of Bradford set out the purpose of medical research which aims to evaluate the factors responsible for increasing the risk of neutropenia in palliative lung cancer patients and if dose reducing appropriately, will lower further incidences of neutropenia. This will reduce neutropenia related hospital admissions and also improve patient outcome by reducing chemotherapy delays.

The study will involve a retrospective case note analysis of patients on palliative lung cancer treatment who have undergone a dose reduction for neutropenia. The project aims to understand whether a predictive model can be designed to recommend a dose reduction based on patient factors such as kidney/ liver impairment or co-morbidities. Eligible patients will be identified from the Chemocare database, the electronic prescribing software for all chemotherapy treatment, by the database manager. Confidential patient information relating to the eligible patient cohort will be transferred to the main applicant, to enable wider patient records to be accessed to extract relevant information for analysis.

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

Confidential patient information requested

Cohort

The cohort would consist of palliative lung cancer patients who received chemotherapy in the 2017 calendar year at any hospital in South Yorkshire. 385 patients in total will be included in the study (360 phase one and 15 phase 2).

The main applicant, who is not considered part of the direct care team, will use NHS number to access complete patient records in order to extract the relevant information required for analysis. The following items of confidential patient information are required for analysis:

- Date of birth – converted to age,
- Sex,
- Ethnicity.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members recognised that gaining further knowledge around the factors which increase neutropenia in this patient population was within the public interest, as this may lead to improved care pathways.

Practicable alternatives

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

- Feasibility of consent

The Group was assured that consent was not feasible for the project due to the poor prognosis of the retrospective patient cohort which would be included. It was recognised that it was likely that a significant proportion of patients would be deceased. No issues were raised in this area.

- Use of anonymised/pseudonymised data

It was recognised that the applicant would need to access to confidential patient information via patient records in order to extract the clinical information which was required for analysis. The applicant had confirmed that this data extraction could not be undertaken by the direct care team. The Group was assured that the project could not be otherwise achieved and raised no issues in this area.

Cohort

The applicant had stated that the study would involve a total of 385 patients across the two phases of the project. Members were unclear whether eligible patients would be identified by the Chemocare Database Manager, prior to the release of any confidential patient information to the applicant. It was agreed that clarification was required in this area to ensure the scope of support being requested was clear.

Justification of identifiers

Members acknowledged that NHS Number would be disclosed to the applicant in order to facilitate access to the wider patient record. The applicant would have access to the complete patient record in order to extract the clinical information required for analysis. It was agreed that the items of confidential patient information requested were proportionate and appropriate to achieve the proposed study aims.

Data Flows

The Group was unclear around the data flows within the study and where confidential patient information would be accessed and by whom. The applicant would be asked to provide a data flow diagram, which clarified this information together with the extraction and disclosure methods and security at each stage.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicant had stated that once the data extraction process was complete, confidential patient information was be deleted from the analysis database. It was further explained that a link key would be retained for the duration of analysis. It was unclear where the key would be held, by whom and for what time period.

The Group also commented that the requirement for the ongoing retention of the linkage key had not been fully justified in the application. Further information would be requested from the applicant.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The applicant had engaged with three patients and two accompanying relatives about the study and sought views around the use of confidential patient information for the project purposes. An overview of the feedback provided which confirmed that the group was overall supportive of the proposal.

The CAG noted that, whilst limited, the activity which has been carried out in this area was appropriate and proportionate to the proposed study and raised no further queries.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and the Data Protection Act 2018.

The applicant had confirmed that the project would be promoted via the Rotherham Trust and Bradford University websites. Copies of the information to be displayed on the websites were not provided for consideration. The Group recognised that, due to the poor prognosis for this patient population, it was likely that the majority of the cohort would be deceased. However, it was agreed that proposed communications strategy was appropriate and would promote the project and the use of confidential patient information within the public domain. It was agreed that the notification text should provide a mechanism for a patient to raise an objection. The CAG requested sight of the website text and an overview of how the objection mechanism would be operated.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score for The Rotherham NHS Foundation Trust had been published in respect of version 14.1 (2017/18) of the toolkit; however, this self-assessment had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. This would need to be addressed by the applicant.

Confidentiality Advisory Group advice conclusion

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

Request for further information (Summary)

1. Clarify how patients would be identified as eligible for inclusion in the study and who would be undertaking this process.

2. Provide a data flow chart for the study, which captures the flow of confidential patient information, identifies who is accessing at each stage and what the extraction and disclosure procedures.

3. Provide justification to support the ongoing retention of the linkage key. Confirm who would retain the key and for what duration.

4. Provide copies of the website text which will be used to facilitate the study communications strategy. An overview of how patient objection would be operated is also required.

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 – Sheffield Teaching Hospitals NHS Foundation Trust has a published satisfactory reviewed grade on V14.1, 2017/18. The Rotherham NHS Foundation Trust has a published self-assessed score on V14.1 2017/17 – this has not been reviewed by NHS Digital**).

g. 18/CAG/0207 – DELIRIUM-PD

Purpose of application

This application from Newcastle University set out the purpose of medical research which aims to follow-up on a previous study, DETERMINE-PD (17/CAG/0191), which was a pilot study that aimed to understand the incidence of delirium in Parkinson's disease.

The aim of the project is to find out how common delirium is in people with Parkinson's, record and describe the symptoms of delirium in Parkinson's. Patients with Parkinson's who are admitted to hospitals in Newcastle upon Tyne will be invited to take part. An electronic alert will notify researchers of their admission; this system is already in use by the hospitals. The applicant will visit participants who consent to participate over consecutive days whilst in hospital and will complete a delirium assessment. Three months after participants' discharge from hospital, they will be invited to a follow up visit where these assessments will be repeated. To find out about people's unique experience of delirium in hospital participants, their relative/carer and healthcare professionals will be invited to take part in interviews. Outputs from the study will include an assessment tool to identify delirium in Parkinson's and dementia, and educational material for people with Parkinson's, their relatives/carers and health professionals. Raising awareness and correctly identifying delirium in Parkinson's could reduce adverse outcomes, such as increased risk of death and dementia.

All patients who attend movement disorder services in Newcastle upon Tyne in treatment of Parkinson's Disease will receive a letter and information sheet about the study which will explain that, should they be admitted to hospital, they will be approached by a researcher about the study. Support is requested to disclose confidential patient information from the Newcastle upon Tyne Hospitals Foundation Trust to the research team to facilitate postal invitations and to enable alerts to be made upon admission to hospitals. This follows the same recruitment methodology that was used in the pilot study, which was supported under reference 17/CAG/0191 which was carried out to inform this larger scale trial.

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

Confidential patient information requested

Cohort

Patients with a diagnosis of Parkinson's disease or Parkinson's disease dementia according to UK Brain Bank Criteria made by a movement disorder specialist, who have attended the Newcastle-upon-Tyne Hospital (NuTH) Foundation NHS Trust movement disorder clinics for the management of their Parkinson's within 18 months of the start of the study. Patients who are subsequently admitted to a hospital within NuTH during the 20 month recruitment period will be approached to participate in the study.

The following items of confidential patient information will be disclosed from Newcastle upon Tyne Hospitals Foundation Trust to facilitate the recruitment process:

- Name – sample validation and invitation process,
- Hospital Number – sample validation and invitation process,
- Full address and postcode – sample validation and invitation process.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members noted that the proposed study was a larger scale trial informed by a previous pilot study, which had tested the recruitment methodology and found this to be successful. The Group was assured by the findings of the pilot study in supporting the recruitment methodology and recognised that the undertaking of the larger scale trial was within the public interest.

Practicable alternatives

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

- Feasibility of consent

The Group recognised that support under the Regulations was being sought to enable the eligible patient cohort to be informed about the proposed trial and subsequently be approached for consent to participate. It was not feasible to seek prior consent for this process from patients. The applicant had provided evidence to support this methodology from the findings of the pilot study. The CAG raised no issues in this area and was content to provide a recommendation of support for the project.

- Use of anonymised/pseudonymised data

Access to confidential patient information was required in order to facilitate the invitation process which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

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

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Members noted the proposed exit strategy from support was the provision of patient consent to participate in the study. For patients who raise an objection around being approached to participate in the study, or decline participation, confidential patient information will be retained for the 20 month recruitment period to ensure these individuals were not inadvertently re-approached about the study. Following the recruitment period, this information would be destroyed. The Group was assured by the proposed exit strategy and raised no issues 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. Members recognised that there had been ongoing patient and public involvement in the

overarching programme, which also included feedback from the pilot study. The applicant had planned ongoing activity in this area as the study progressed. The Group was satisfied that the activity in this area was appropriate and proportionate to the proposal and raised no issues.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 2018. The Group recognised that all patients who may be eligible to participate in the study would receive a targeted notification, to inform them about the study and advise that they would be approached for consent if they were admitted to hospital. Patients were provided with the means to raise an objection at this point, to prevent any further contact or approach from the research team. This approach had been trialled in the pilot study and was found to be successful. Members were assured by the findings of the pilot study to support this methodology and raised no issues in this area.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score for Newcastle upon Tyne Hospitals NHS Foundation Trust had been published in respect of version 14.1 (2017/18) of the toolkit; however, this self-assessment had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. This would need to be addressed by the applicant prior to any final 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. A copy of the favourable ethical opinion from the REC would need to be provided prior to any final recommendation of support coming into effect.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the requirements of the General Data Protection Regulations (GDPR) implemented through the Data Protection Act 2018. Confirmation is required around the lawful basis which is being relied upon for processing in relation to Article 6 and Article 9 of the GDPR for the purposes of the application activity. Clarification would be sought from the applicant prior to any final recommendation of support coming into effect.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Confirm what lawful basis which is being relied upon for data processing in the study in relation to Article 6 and Article 9 of the GDPR.

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 – Newcastle upon Tyne Hospitals NHS Foundation Trust has a self-assessed score on V14.1, 2017/18 – review is required from NHS Digital**).

4. RESUBMITTED APPLICATIONS – Research

a. 18/CAG/0199 (Resubmission of 18/CAG/0160) – The effect of early cryoprecipitate transfusion versus standard care in women who develop severe postpartum haemorrhage: A pilot cluster randomised trial

Purpose of application

This application from Queen Mary University of London set out the purpose of medical research which aims to investigate the feasibility of administering cryoprecipitate early (within 90 minutes of major haemorrhage protocol activation) in pregnant women who are actively bleeding and who require blood transfusion within 24 hrs of delivery, as compared to standard treatment, where cryoprecipitate is given later or not at all.

There will be four participating sites within the study (three within Barts Trust) and randomisation will occur at site level (cluster randomisation). The intervention group will deliver cryoprecipitate within 90 minutes to any women who meet the eligibility criteria. The control arm will continue to give cryoprecipitate in response to low fibrinogen level or if they have received massive transfusion, defined as greater than eight units of red blood cells. The study will be fully unblinded to participants, clinical staff and the central research team.

Data will be collected retrospectively to enable this to be undertaken with patient consent. Routine baseline and clinical information will also be collected from all women who fulfil study criteria up to hospital discharge, or 28 days post-delivery (whichever is sooner).

The application has been submitted to seek support under the Regulations to allow the research team access to patient records to identify those eligible for inclusion to enable an approach for consent to be made. Support is also sought for a sub-cohort of women who die or are discharged from hospital prior to the approach to consent and/or the approach to a personal/professional consultee being made, in the event that the patient is seemed to lack capacity to consent.

There are further future elements to the study which will be undertaken on a consented basis which will include collection of outcome data at three months, MFI Questionnaire, qualitative interviews and collection of residual blood samples from hospitals. These are out of scope for the CAG consideration as patients will consent to these elements.

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

Confidential patient information requested

Cohort

Pregnant women at greater than 20 weeks gestation who are actively bleeding after childbirth (up to 24 hrs), and for whom major haemorrhage protocol has been activated, and/or transfusion of at least one unit of red blood cells has been started for treatment of bleeding. 200 patients will be recruited to the study across the two participating Trusts. The scope of support under the Regulations extends to the collection of data in relation to women who die or are discharged from hospital before an approach for consent is made.

The research team would have access to complete patient records of all women who deliver at the participating sites. The following items of confidential patient information are required for the purposes of sample validation and to enable an approach for consent to be made:

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

Confidentiality Advisory Group advice

The CAG recognised that the presented application was a resubmission of 18/CAG/0160 which was considered at the CAG meeting held on 04 October 2018. Consideration was given to the areas of further information requested only, as it was acknowledged that the CAG was satisfied with the wider areas of the application.

This letter should be read in conjunction with the outcome dated the 23 October 2018.

Public interest

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

Scope of Support Requested

The Group commented that the application was much improved from the initial submission. The study methodology had been revised and would be operated on a consented model. The applicant had also incorporated consultation processes to comply with the requirements of the Mental Capacity Act 2005. Support under the Regulations was still required to enable the eligible patient cohort to be identified from medical records. Members recognised that whilst the proposed recruitment methodology would still breach the common law duty of confidentiality, this was necessary to enable the approach for consent to be made. Patient-facing materials had also been updated to reflect how patients were identified for invitation to the study.

The applicants also sought support under the Regulations for a sub-cohort of the overall patient group, who were discharged from hospital or had died prior to an approach for consent being made. The applicant confirmed that the central research team would monitor the number of instances where an approach to consent was not been made. This was in order to minimise the numbers in this sub-cohort by taking appropriate action if there as a high number of patients reported.

The CAG recognised that the proposed application was a feasibility study which aimed to trial the methodology to inform a larger-scale trial. It was recognised that the consenting process would be undertaken by the research team, who would also be monitoring the numbers of patients for whom consent was not taken. Members were content to provide a recommendation of support for the trial study on the basis that the number of patients who were not approached for consent would help inform the case ascertainment requirements for any larger scale study. It was agreed that a report would be required at the time of first annual review around the number of patients who were deceased or discharged before being approached for their consent for information.

Practicable alternatives

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

- Feasibility of consent

The Group was assured that it was not feasible to seek prior consent from the patients around the access to confidential patient information to identify eligible participants. It was recognised that patients would be subsequently be approached for consent to participate in the study. Members raised no issues in this area; however, it was recommended that the researcher should be introduced to the patient by a member of the direct care team when making the approach for consent.

- Use of anonymised/pseudonymised data

Access to confidential patient information was required to enable the patient cohort to be identified, which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

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

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicant had established a patient consenting model as an exit strategy from support under the Regulations. For those patients who were discharged or deceased prior to an approach to consent being made, a pseudonymised dataset would be extracted for analysis purposes.

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 compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Provisional)

1. A report should be provided at the time of first annual review around the number of patients who died or were discharged prior to a formal approach for consent being made.

2. Favourable opinion from a Research Ethics Committee (**Pending**).

3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Barts Health NHS Trust and Homerton University Hospital NHS Foundation Trust both have a published reviewed grade on V14.1 2017/18**).

5. MINUTES OF THE MEETING HELD ON 04 OCTOBER 2018

The minutes were accepted as an accurate record of proceedings with no revisions.

6. ANY OTHER BUSINESS

The CAG received a report from the Chairman for November 2018.

The Confidentiality Advice Team requested Members expense submissions to be made in a timely fashion as the financial year end approached.

Members were reminded that any educational items to be explored should be provided to the Chair Team and the CAT for follow-up.

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