NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

28 September 2017 at Barlow House, M1 3DZ

Group Members:

Name	*Present*	*Notes*
Dr William Bernal	Yes	
Ms Sophie Brannan	Yes	Lay
Mr Anthony Kane	Yes	Lay
Dr Rachel Knowles	Yes	
Mr Andrew Melville	Yes	Lay
Dr Mark Taylor	Yes	Chair
Mr Marc Taylor	Yes	
Ms Gillian Wells	Yes	Lay

Also in attendance:

Name	*Present*	*Notes*
Miss Kathryn Murray	In Attendance	Senior Confidentiality Advisor

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies

Apologies were received in advance of the meeting from Ms Kim Kingan.

Declarations of Interest

Agenda Item 5.c. Application Reference 17CAG0156: Mr Anthony Kane declared a potential conflict of interest in considering the application. The CAG agreed that Mr Kane could remain present during discussions, but would not participate in the consideration or the recommendation on the project.

No other interests were declared.

2. APPROVAL DECISIONS

The following was shared with the CAG for information.

Secretary of State Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the 24 August 2017 meeting applications.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 24 August 2017 meeting applications.

3. CONSIDERATION ITEMS

a. Education Items – for discussion

The Chair explained that education items had been added to the agenda as a standing item once again and provided an opportunity for Members to suggest any areas in which they would benefit from additional training.

The following suggestions were put forward and it was agreed that these would be logged at office level:

- HRA Approval – overview of the process and areas considered,
- NHS Scotland Public Benefit and Privacy Panel – overview of the processes,
- Refresher session on research databases – as a review of a session delivered to the CAG in the past.

4. RESUBMITTED APPLICATIONS – Non-research

a. 17CAG0140 (Resubmission of 16CAG0152) National Bone and Joint Infection Registry

Context

Purpose of Application

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

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

Confidential Patient Information Requested

Cohort

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

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

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

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

Confidentiality Advisory Group Advice

This application was a resubmission of project reference 16/CAG/0152, which was considered at the CAG meeting held on 01 December 2016. Members considered the points for additional information which had been raised as part of the previous review, together with the response provided by the applicants. The Group acknowledged the work which had been undertaken by the applicants in the intervening period around the application.

Public Interest

The CAG remained assured that there was a medical purpose in the activity described; however, Members raised queries around the public interest in the activity. It was acknowledged that the applicants had provided further information in relation to the complex care pathways and specialities involved in the treating this patient cohort. The Group was unclear of the data collection arrangements which were in place for the project and whether the applicants would achieve a great enough case ascertainment to enable the public interest in the activity to be realised.

Members noted that Public Health England currently ran a surgical infections audit which achieved comprehensive ascertainment and it was commented that it was unclear from the detail provided within the application how this proposed activity would supplement the information which was available from this national audit. The CAG agreed that further information was required from the applicants around the data collection systems to gain a clear understanding of how they intended to capture cases across the wide range of specialities involved in the care of this patient cohort. It would also be queried whether the applicants had been in correspondence with PHE or HQIP to discuss possible interactions between the proposed registry and existing national audit programmes.

The Group reiterated that it was assured by the evidence which had been presented to support the project; however, it also needed to be assured that the methodology which was established for the project would achieve a sufficient case ascertainment.

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

It was clarified within the documentation that the treatment care pathway for this patient cohort was complex and involved various specialist care teams and institutions which may not always interact with one another. It was further explained that the treatment pathways for this patient group may differ around the country. Members were assured that, due to the diverse range of clinicians involved in the care of this patient group, there was no universal point which presented the opportunity for consent to be taken. The Group was satisfied that for this reason, consent was not feasible for the proposed activity.

- Use of anonymised/pseudonymised data

The CAG acknowledged that access to confidential patient information was required to facilitate the data linkage with the HES dataset held by NHS Digital.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. The CAG was satisfied that the identifiers proposed were appropriate to the proposed activity and the facilitation of linkage with the HES dataset.

Data Flows

Members discussed the data flows in the project and it was acknowledged that registry data would be entered directly into an online platform for the database which will be facilitated by Dendrite. The applicants had advised that there would be additional data linkage with the HES dataset held by NHS Digital; however, the Group was unclear how often this linkage would be undertaken and what data was expected to be returned. It was agreed that further information was required in this area to gain a better understanding of the proposed uses of the data. It was also queried whether a formal data sharing agreement had been established between Dendrite and each of the participating Trusts, as it was noted that this would provide evidence that they were meeting their responsibilities as data controllers and data processors under the Data Protection Act 1998 as well as using appropriate technical and organisational measures to protect the data flows described in this application.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicants had stated within the application that anonymisation would take place at the first possible instance; however, it was not clear when this would be carried out. It was further noted that the applicants had requested ongoing support as it was unclear from the outset what additional data linkages may be required to enable the registry to be the most effective. Members commented that the applicants had revised the application and were no longer proposing linkage with the National Joint Registry or the National Hip Fracture Registry, so it was unclear what further data sources they envisaged linking the proposed registry with.

The Group agreed that further information was required from the applicants in this area to ensure that, should any recommendation of support be made in the future, this was for an agreed timescale and purpose. It was further commented that additional ways to reduce the identifiability of the data set should be explored and a clearer steer provided around the plans to anonymise the dataset. Whilst the Group was

assured that consent was not feasible for the project from the outset, it was acknowledged that the patient population in question were likely to be the subject of inpatient stays, which provided some possibility for consent to be sought. Members recommended that the applicants should also be working towards ways to improve a consenting mechanism for the registry as an exit strategy from support under the Regulations.

Patient and Public Involvement and Engagement

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

The CAG considered the information provided by the applicants around the involvement and engagement work which had been undertaken and it was agreed that this is appropriate and relevant to the activity proposed. Members agreed that an ongoing programme of activity in this area would be required, acknowledging that the applicants had requested ongoing support under the Regulations for the registry. The applicants would be asked to provide a plan for ongoing public and patient engagement and involvement activities, which will facilitate ongoing interaction, for which ongoing reports would be required.

Patient Notification and Dissent

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

Members considered the detail of the patient information leaflet and poster which had been supplied as part of the documentation pack to facilitate the notification mechanisms for the project activity. In discussion, the CAG noted that the information leaflet only referenced some of the items of confidential patient information which would be collated via the registry. It was suggested that the document could be misleading by making reference to a subset of the data which would be collected and the Group agreed that the document would require revision to include each of the patient identifiers which would be entered into the registry.

The CAG further commented that both the information leaflet and the poster stated that, through inclusion in the registry, there would be no access to information which was individually identifiable which was not accurate. Members agreed that the documents required further revision to accurately explain what data would be included in the registry, which organisations would have access to this data and what it would be used for, including explanation of links with wider NHS datasets.

It was noted from information included within a supporting project document that the majority of patients within this profile would pass through a specialist bone and joint registry centre and it was recommended that links were established with these centres to ensure wide coverage with the patient notification materials.

The Group was satisfied that, with the inclusion of the relevant contact details within the documents, the opt-out mechanism had been appropriately described.

Confidentiality Advisory Group Advice Conclusion

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

Further Information Required (Summary)

The following information should be provided to allow the CAG to continue their consideration of the application.

1. Further information is required around the data collection methodology – a clearer articulation of the proposed methodology should be provided, taking the following points into account:
   a. Clarify how case ascertainment will be maximised, also addressing how it will be known how accurate the captured sample if against the true patient cohort,
   b. Explain what additional purposes this proposed registry will fulfil that are not currently achieved by the national surgical infections audit,
   c. Confirm if there has been any previous correspondence with Public Health England and/or HQIP around potential crossover with existing audit programmes.
2. Further information is required around the data flows and proposed linkages within the project – response should be provided, addressing the following points:
   a. Confirm how often it is proposed to facilitate data linkage with the HES dataset held by NHS Digital and detail what information will be returned when linkage is undertaken,
   b. Clarify whether there has been any correspondence with NHS Digital around this proposed data linkage and provide an overview of this,
   c. It is unclear whether data sharing agreements have been drawn up between the organisations involved in the project, i.e. Dendrite, participating Trusts and NHS Digital – provide confirmation and copies of any documentation where appropriate, to provide an overview of the various responsibilities within the project.
3. Further information is required in relation to the exit strategy to move away from support under the Regulations for the registry – response should be provided addressing the following points:
   a. A more definitive plan should be provided in relation to future data linkages, providing detail of what data sources it would be anticipated that the registry would seek linkage with and for what purposes,
   b. Consider others ways in which the identifiability of the dataset retained could be reduced,
   c. Provide a more definitive plan in relation to the anonymisation of the dataset,
   d. Consider ways in which a consenting mechanism could be developed for the registry, to enable an exit strategy from support under the Regulations to be achieved through consent.
4. Public and Patient Involvement and Engagement – provide a detailed plan of how activity in this area will be continued as the project progresses and the registry is established.
5. Patient Notifications and Dissent – revise the documentation as follows to address the outstanding issues:
   a. Patient Information Leaflet – revisions should be made to the document as follows:
   i. Revise the list of confidential patient information items to include details of all patient identifiers which will be collated within the registry,
   ii. Provide a clear and accurate overview of the organisations involved with the registry, explaining who will have access to the data and in what format (identifiable, aggregated anonymised etc.) and what it will be used for, including an overview of links with wider NHS datasets.
   b. Poster – revisions should be made to the document as follows:
   i. Provide a clear and accurate overview of the organisations involved with the registry, explaining who will have access to the data and in what format (identifiable, aggregated anonymised etc.) and what it will be used for, including an overview of links with wider NHS datasets.

5. NEW APPLICATIONS – Research

a. 17CAG0148 – iMANAGE

Context

Purpose of Application

This application from Kings College London sets out the purpose of medical research which proposes to construct a risk model to predict neutropenic sepsis by analysing retrospectively collected patient data from Guy's and St Thomas' NHS Foundation Trust. The data includes anonymised patient characteristics,

chemotherapy treatment schedules, blood test results, complications and admissions to hospital. The collection of retrospectively collected routine data, which is anonymised, will be used to develop a model.

This work forms part of a European Union Horizon 2020 project, iManage Cancer. The risk model will be incorporated into an 'App' as part of a larger collection of tools and aids for clinicians, in conjunction with their patients, to assist in the management of their cancer care.

The research team will have access to patient identifiable data, only, to fill in any gaps as part of the validation process of the data received. This will be done after extraction by the direct healthcare team. After this, data will be anonymised for analysis.

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

Confidential Patient Information Requested

Cohort

Patients aged 18 and over with a new diagnosis of breast or prostate cancer between May 2010 and May 2016. This will encompass 850 patients.

The following data items will be extracted from patient records by the direct care team:

- NHS number,
- Date of birth,
- Hospital ID.

The research team will have access to the above details in order to validate the data extraction and access patient records to extract further details from the wider clinical information, where the direct care team extraction was incomplete. Once validation has been undertaken, the direct care team will then anonymise the dataset for analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application identified a medical purpose which was in the public interest, due to the potential benefit for patient care if the applicants are able to construct the risk model as predicted.

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 noted that whilst the proposed sample was limited at 850 patients, it was recognised that it was likely that a proportion of the historical cohort would be deceased and consent would not be feasible. It was noted that seeking consent from living patients would involve a greater disclosure than that which was required to achieve the study aims and Members were assured that consent was not feasible for the project.

- Use of anonymised/pseudonymised data

The CAG acknowledged that the study analysis would be undertaken on a de-personalised dataset; however, the applicants would require access to confidential patient information for those patients with an incomplete data extraction, as undertaken by the direct care team, to allow the omitted data to be collected from the patient's record. Members requested clarification that the research team would only have access to the medical records for the subset of patients with an incomplete data extraction.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. Members acknowledged that the applicants would not retain any identifiable information for analysis; however, access to patient records was required to complete the data extraction. The Group was assured that the time limited access to identifiable information appeared to be justified to the activity proposed.

Exit Strategy

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

The Group was unclear from the detail provided within the application how long the applicants intended to retain confidential patient information. It was agreed that clarification was required here as there maybe the requirement to separate identifiable data items from the clinical information if these were to be retained for some time.

Patient and Public Involvement and Engagement

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

The Group acknowledged that the applicants were taking the study proposal to the Independent Cancer Patients Voice group to allow discussion at their forum meeting. It was agreed that an overview of the engagement activity would be required together with any feedback from the patient group for consideration.

Patient Notification and Dissent

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

Members considered the patient notification arrangements which had been put in place for the study and it was commented that the iManage Cancer website did not appear to be the appropriate place to facilitate the system of notification and dissent. It was suggested that using the Guy's and St Thomas' Trust and King's College London websites would be more appropriate for digital promotion. The Group further commented that, in order to operate a meaningful objection system, the applicants would need to ensure that the notification materials were displayed for an agreed period of time ahead of the data extraction occurring, to enable a patient to raise an objection.

Members also identified within the application that the depersonalised patient data would also be analysed by Philips as part of the project. Members noted that ordinarily there was greater concern amongst patients when commercial organisations were involved in the analysis of health data and it was agreed that this should be made clear in the patient notification materials.

The CAG agreed that a revised patient notification and dissent plan would be required for consideration, together with copies of the material to be displayed. This should provide an overview of the intended display time ahead of the data extraction together with an explanation of how any patient dissent would be respected.

Confidentiality Advisory Group Advice Conclusion

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

Request for Further Information

1. Clarify how long confidential patient information will be retained for. It was noted that if this was an extended duration, there may be a requirement to separate the identifiable and clinical information for storage.
2. Provide confirmation that the researcher will only access the patient's medical record when the data extraction undertaken by the direct care team was incomplete.
3. Provide an overview of the engagement activity which was undertaken with the Independent Cancer Patients Voice forum, together with any feedback which was provided.
4. Patient Notifications and Dissent – a revised plan for patient notifications, or information which will be made publicly available to promote the research, is required to address the following points:
    a. The proposed websites to display information about the research on should be reconsidered in light of the above discussion – confirm the revised digital platforms which will be used to promote the study,
    b. Copies of the notification materials should be provided for consideration,
    c. The information materials should clearly explain that the depersonalised patient information with be analysed by commercial organisations,
    d. An overview should be provided around the patient notification plan for the study, explaining the lead time during which information will be made available, ahead of the data extraction being undertaken,
    e. A clear explanation should be provided around how a patient can raise an objection to the use of their data together with clarification of how this would be respected.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee. **(Pending)**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Guy's and St Thomas' NHS Foundation Trust 92% satisfactory on version 14 2016/17).**

b. 17CAG0151 – ARREST

Context

<u>Purpose of Application</u>

This application from St Thomas' Hospital sets out the purpose of medical research through a London-based multi-centre randomised controlled trial comparing expedited transfer to a specialised Cardiac Arrest Centre (CAC) to the current standard of care, which is transfer to the geographically closest emergency department, for a patient having a cardiac arrest without ST elevation (an abnormal electrical activity in the heart that is seen on the patient's ECG). A CAC is a specialised centre for treating patients with a heart

attack and expedited transfer to a CAC is standard of care for patients having a cardiac arrest with ST elevation.

This research takes place in an emergency context. The acute nature of the cardiac arrest and the time critical component to randomisation requires immediate action. The applicants have therefore requested and been approved a consent waiver for this trial from the Research Ethics Committee (REC) under the auspices of emergency research section 32(9) of the Mental Capacity Act 2005.

Support is requested to allow a research paramedic in the Clinical Audit and Research Unit (CARU) team at the London Ambulance Service (LAS), who is outside of the direct care team, access to the Patient Record Form which has been gathered by the paramedics. The research paramedic will then approach the individual to seek their consent for continuation in the trial.

The applicants state that gathering data on this full patient group is crucial for the success of the trial; however, it is acknowledged that this is complex patient group. The applicants are seeking support under the Regulations for the use of data in the following cases:

1. To allow the research paramedic access to confidential information on the patient record form to gather anonymised data in relation to patients who die before regaining capacity and/or before a personal or professional consultee can give consent.
2. Data collected up to the time a patient is approached and declines consent, unless the patient specifically requested that this data is deleted.
3. Data collected on patients that have been discharged from hospital before they or a consultee could be approached about consent.
4. To allow mortality tracking of all patients within groups two and three detailed above, up to 12 months post-event, by a research nurse at St Thomas' Hospital London.

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

Confidential Patient Information Requested

Cohort

Patients with suspected out-of-hospital cardiac arrest, male or female aged 18 and over. There will be 860 participants in total, with 430 in each arm of the trial.

The research paramedic will require access to the full medical record for all patients. Those who are approached for consent and provide it will no longer require support under the Regulations.

The only item of confidential patient information which will be extracted from the patient's record with support under the Regulations will be NHS Number. This will be transferred in an encrypted fashion by the research paramedic to a specific research nurse at St Thomas' Hospital. The research nurse will have access to the encryption code, to enable the NHS Number to be transferred back to true format to enable mortality status to be checked up to one year post-event, at which stage the patient's NHS number would be destroyed. If the patient has subsequently died in the interim year, the research nurse will record date of death in a time range from randomisation to ensure that the date of death cannot be worked out: <48 hours, 48 hours to 7 days, 8 days to 14 days, 15 to 30 days and >30 days.

Confidentiality Advisory Group Advice

Public Interest

Members agreed that the application defined a medical purpose which 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 CAG acknowledged that the applicants were seeking support under the Regulations to enable those patients who had been randomised into the trial to be approached for consent for their continued involvement in the study. Members were assured that access to confidential patient information was required in order to facilitate this formal approach for consent.

It was recognised that some of the patient cohort would not survive the cardiac arrest incident and the Group was content to make a recommendation of support to enable the research paramedic to access the medical records of this sub-group of patients, to extract an anonymous dataset for use in analysis.

Members raised concerns around the wider points of the study for which the applicants were seeking support under the Regulations. It was acknowledged that, if a patient was approached for consent and declined to provide it, this presented an opportunity to allow the applicants to discuss exactly what the patient is dissenting to. This could include discussion around the retention of their data up to the point consent was declined and the future tracking of mortality status. The CAG agreed that it was unable to provide a recommendation for support under the Regulations in these circumstances, as there was a practicable alternative, through the discussion with the patient.

- Non-Response to a Request for Consent

The applicants had identified a sub-cohort of patients whom had survived the cardiac arrest incident, but were discharged from hospital before the research paramedic was able to approach the patient for consent. In this instance, the applicants were proposing contacting the patients on two occasions to seek formal consent for their continued involvement in the study. If no response was received to the formal consent contact, the applicants were requesting support under the Regulations to retain the dataset on this patient group and undertake mortality tracking.

The CAG advised that support could not be sought via the Regulations to access and process the data of patients who had been approached for formal consent and had either dissented or chosen not to respond to the request. In light of this agreed position, the CAG was unable to make a positive recommendation of support under the Regulations for this request.

Members had considered information in relation to a historic application which was referenced as precedent within the submission. The PARAMEDIC2 project had received a recommendation of support for similar activity also involving patients in the emergency setting who had suffered a cardiac arrest. The Group identified that, in this historic project, those patients who were discharged from hospital before formal consent could be taken, were provided with written information about the project and the opportunity to opt-out on the ongoing use of their data, rather than formal consent to participate in the study. The CAG recommended that the applicants consider revising their proposed methodology to align with that which was previously supported for the PARAMEDIC2 project. It was noted that this would involve a revision of the information materials which had been prepared and approved by the Research Ethics Committee, to bring these in line with the revised methodology. Members further commented that feedback would be required at annual review to understand the number of patients who had been discharged from hospital before they had been approached for consent, together with details of how many patients had formally opted out upon receipt of the materials.

The Group acknowledged that the submission had included copies of all of the participant information and consent materials. Whilst it was understood that review of patient information and consent materials was within the remit of the Research Ethics Committee, it was commented that some of the detail included

within the documentation around the anonymisation of patient information was unclear and would benefit from revision.

- Use of anonymised/pseudonymised data

The applicants were undertaking analysis on an anonymised dataset for those patients whose data was entered into the study with support under the Regulations. It was also accepted that the initial access to confidential patient information was required to enable an approach for consent to be made. It was acknowledged that the NHS number would be retained in an encrypted format to enable mortality status to be tracked; however, this follow-up could not be achieved without access to the identifiable data item. Members were assured that access to confidential patient information was required to facilitate the project.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth.

Members sought clarification of whether any cause of death would be recorded as part of the mortality tracking.

Exit Strategy

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

Members were assured that relevant exit strategies had been proposed from the requirement for continued support under the Regulations; however, it was identified within the application that study data would be retained for 15 years. It was agreed that the applicants would be asked to clarify in what format this data would be held.

Patient and Public Involvement and Engagement

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

The Group recognised that the applicants had included two patient representatives on the Trial Steering Committee and whilst it was agreed that this was a positive step, additional work should be undertaken to improve the patient and public involvement and engagement with the trial. It was recommended that a wider patient group be approached about the trial, together with appropriate relatives and carers to allow wider input into the trial.

Patient Notification and Dissent

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

Members suggested that the patient notification system could be extended to a wider geographical coverage, acknowledging that the study is being undertaken London-wide. It was recommended that the applicants extend the notification mechanisms identified across the wider Trusts which will be involved in the study. It was further identified that information which would be displayed on the study website had been written in the circumstances that the patient was deceased and would be placed under a header of information for ‘relatives, friends and partners’, which excluded the patients themselves. The applicants

would be asked to reconsider the audience and placement of information on the study website to make this more accessible to the patients in the first instance.

A query had been raised in advance of the meeting around the possibility of enabling patients to register dissent to being enrolled in the study as a prior objection, should they suffer cardiac arrest in future. It was acknowledged that this was a system which was proposed for the PARAMEDIC2 which operated in the same manner as do not resuscitate wishes, which are reported to the attending paramedics in an emergency call out. The response provided by the applicants did not clearly address the query which was raised and further response would be required to understand whether this was possible for the trial.

Involvement of Third Party Organisations

Confirmation was required from the applicants around whether Rackspace and Sealed Envelope Ltd, the third party organisations involved in the data hosting of the study database, would receive the transfer of confidential patient information without consent. The Group advised that if this was the case, confirmation the NHS IG Toolkit for each organisation would be required to satisfy the security assurance arrangements, as determined in Department of Health policy.

History of the Project

The CAG remained unclear of the history of the project. Whilst it had been acknowledged that the REC opinion had been in place for some time and the applicants had clarified that a pilot study had been undertaken, it remained unclear what changes had been made between the pilot study and the proposed full trial, which had led to the requirement for a submission for CAG consideration. Further information would be required from the applicants in this area.

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. The CAG cannot provide a recommendation of support to retain data and follow-up a patient who has been approached for consent but declines to participate. It is recommended that the consenting process for the project is revised, to enable a discussion to be undertaken around what the patient is dissenting to, to allow data previously collated and follow-up to be undertaken as per the individual's wishes. It is acknowledged that this may require revisions to REC approved documentation to bring in line with the recommendation of support under the Regulations.
2. The methodology to approach patients who have been discharged from hospital before they can be formally approached for consent should be revised in line with that which was previously supported under the PARAMEDIC2 project. This will allow patients the opportunity to opt-out of the use of their data, rather than formally consent. It was acknowledged that this will involve the revision of patient information materials which have existing REC approval to bring in line with the recommendation of support from the CAG.
3. Confirm whether the mortality tracking which will be undertaken will record any cause of death.
4. Confirm the format in which study data will be retained for 15 years following the trial.
5. Provide further information in relation to the history of the trial, detailing how the pilot trial was facilitated, acknowledging that here had been no previous support under the Regulations in place for the activity.
6. Clarify whether Rackspace and Sealed Envelope Ltd. would be receiving or processing any confidential patient information without consent. If so, confirmation would be required around the NHS IG Toolkit arrangements for these organisations.

7. Patient and Public Involvement and Engagement – an revised plan for improved activity is required in this area, taking into account the following points:
   a. A wider group of patients, public, family and carers should be approached about their views on the trial,
   b. A plan should be provided of what activity will be undertaken over the coming year to make improvements in this area.
8. Patient Notifications and Dissent – further information should be provided in this area, addressing the following points and submitting new and/or revised documentation where necessary:
   a. Information about the study should be displayed more widely across the websites and within the relevant clinical areas of the sites involved in the study,
   b. The information which was submitted for the study website should be revised to address a wider audience, not just the potential bereaved relatives and friends of a patient enrolled in the trial who did not survive the cardiac arrest,
   c. Reconsider the possibility of establishing an advance dissenting process, which will enable an individual to lodge an objection to being enrolled in the project I the event they should suffer a heart attack. Provide details of how the system would operate, or further rationale to support why this is not feasible.

Recommendation:

1. When making revisions to the patient information materials in light of points one and two detailed above, it was recommended that the information included within the documents around the anonymisation of information be reconsidered and revised where appropriate.

Specific Conditions of Support (Provisional)

1. Support extends to allow the research paramedic involved in the trial access the patient records enrolled into the study, to facilitate an approach to be made for formal consent.
2. Support cannot be extended to any patient who is approached for formal consent to participate and either declines to provide consent or fails to respond to the request.
3. An overview would be required at the time of first annual review around the number of patients who were enrolled in the trial, but were discharged from hospital prior to an approach for consent to be made. Details would also be required around how many patients opted out from the use of their data, post-discharge from hospital in this circumstance.
4. Favourable opinion from a Research Ethics Committee. **(Pending – revised documentation to be supplied to the REC).**
5. Confirmation from the IGT Team at the NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Pending - Guy's and St Thomas' NHS Foundation Trust IGT shows a self-assessed grade of 92% satisfactory on Version 14, 2016/17, London Ambulance Service shows a self-assessed grade of 83% satisfactory on Version 14, 2016/17 – this has not yet been reviewed by NHS Digital).**

c. 17CAG0156 – OnCoRe Database

Context

Purpose of application

This application from the Christie NHS Foundation Trust set out the purpose of establishment of a research database which will store data on patients who have been diagnosed with rectal cancer and treated with pre-operative radiotherapy or chemo-radiotherapy. In 10-20% of patients, this treatment results in a complete disappearance of the rectal tumour (known as a complete response) and it is data for these patients that the database will focus.

Upon establishment, newly diagnosed patients will be included in the registry on a fully consented basis. The applicants are seeking support to include a historic patient cohort of over 1,000 patients from three previously registered audits with the Christie NHS Foundation Trust within the database. The application to the CAG concerns this historic patient cohort only.

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

Confidential Patient Information Requested

Cohort

The patient cohort for consideration within the CAG application consists of 1126 patients which were previously included within three local audits which were undertaken by the Christie NHS Foundation Trust.

Information will be transferred from the existing audit datasets into the new database; however, the applicants have confirmed that NHS number only will be transferred in its true format to enable follow-up of the patients to be undertaken. Follow-up would be undertaken at a local level between the applying Trust and its immediate referral centres within Greater Manchester; parts of Merseyside; South Lancashire; and North Wales.

The following data items are required:

- NHS/CHI Number – linkage and analysis,
- Month and year of birth – analysis,
- District Level postcode – analysis,
- Gender – analysis.

Confidentiality Advisory Group advice

Public Interest

Members agreed that there was clear medical purpose and public interest within the application activity.

Practicable Alternatives

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

- Feasibility of consent

The CAG recognised that it was likely that a percentage of the historic patient cohort would be deceased and for those who were living, there was potential that the contact information held for them was now outdated. Members were assured that consent was not feasible for this patient group.

- Use of anonymised/pseudonymised data

Members were assured that the required follow-up of the historical patient cohort could not be facilitated without access to the confidential patient information requested.

Justification of identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth.

The Group identified that the applicants were requesting district level postcode, which it was understood to be required to facilitate the calculation of deprivation scoring. Further information was required from the applicants as it was noted that deprivation score could not be calculated from the district level postcode. The applicants would either require the full postcode to undertake the calculation or provide further explanation to justify the request for district level postcode.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicants have requested ongoing support for five years in line with the ethical approval which will be granted the Research Ethics Committee. At this point, a reassessment would be undertaken to determine the ongoing need for support under the Regulations. Members were assured that the applicants had limited the information requested for the historical cohort to be the minimum required to facilitate the follow-up.

Patient and Public Involvement and Engagement

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

The CAG acknowledged that the applicants had a scheduled engagement event with a patient group and it was agreed that feedback would be required from this session to support the application. Members also agreed that a plan for ongoing patient and public engagement and involvement would need to be established to be undertaken following the establishment of the database. Details of the proposed activity would be required for consideration before a recommendation of support could be provided and it was agreed that feedback against the actual activity undertaken would be required at annual review.

Patient Notification and Dissent

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

The Group discussed the patient notification proposals for the project and it was acknowledged that whilst the activity which was proposed was relevant, the scope of the notification mechanism could be widened. It was suggested that information could be displayed in the outpatient clinics ran by the Clinical Nurse Specialist, who would be providing the follow-up data on the patients and would also be likely to treat this patient cohort.

Onward Release of Patient Data

The CAG queried whether the applicants had established a data sharing agreement for onward disclosure of anonymous data from the database, as it was acknowledged from the application form that it was intended that the database would have generic ethical approval to supply data to the wider researcher community.

Patient Information Materials

The CAG considered the patient information materials which had been included within the submission to facilitate consent from those patients prospectively enrolled in the database. It was noted that there was some contradiction within the documents as to whether the data retained in the database was anonymous or identifiable and it was recommended that the applicants consider revising the detail.

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 whether district level postcode has been requested to facilitate with the calculation of deprivation scores. If so, revise the request to cover full postcode.
2. Patient and Public Involvement and Engagement – further information is required in this area to address the following points:
   a. Provide an overview of the engagement event which was held with the BRC PPI/E meeting, together with feedback provided by the attendees,
   b. Provide details of an ongoing plan for patient and public involvement and engagement to be undertaken over the first year of the project.
3. Patient Notifications and Dissent – further work is required in this area to address the following point:
   a. Information about the project should be displayed in the outpatient clinics of the Clinical Nurse Specialist, to maximise the potential for the historical cohort to see the information.
4. Provide further information around the data access arrangements which will be put in place when facilitating release from the database. Information should also be provided in relation to any controls which would be put in place around data release and any constraints which would be placed on the type of organisation that could apply for access to the data.

Recommendation:

1. Detail within the patient information materials requires revision to accurately reference the form in which patient data is retained within the database.

Specific Conditions of Support (Provisional)

1. Patient and Public Involvement and Engagement – provide a report at the time of first annual review of the actual activity undertaken against the plan as set out in point 2.b. above.
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 – The Christie NHS Foundation Trust shows a self-assessed grade of 85% on Version 14, 2016/17. Email confirmation received 12/09/2017 that this is satisfactory).**

d. 17CAG0158 – Suicide in the Criminal Justice System

Context

Purpose of Application

This application from the University of Manchester sets out the purpose of medical research into suicide amongst prisoners. This study will conduct an independent case series examining all self-inflicted deaths in prisons in England and Wales between 2016 and 2019. The applicants will examine trends over time and explore what may have contributed to the rise in self-inflicted deaths in custody. They will also examine specific groups (such as remand, women, older prisoners) and the circumstances of suicide to make recommendations regarding the recognition, assessment and management of suicide risk and related issues of general mental health care and training needs of staff. Furthermore, although deaths by those in, or shortly after leaving police custody, and those on community supervision or licence annually account for smaller numbers than self-inflicted deaths in prison, the risk is pervasive throughout the Criminal Justice

System. Therefore this study will conduct a scoping exercise to ascertain what procedures are in place, and what data are collected, when a suicide occurs in the wider Criminal Justice System. This will add to a comprehensive body of information about self-inflicted deaths across the criminal justice pathway in order to inform prevention policies going forward.

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

Confidential Patient Information Requested

Cohort
All deaths in prisons in England and Wales classified as self-inflicted from 1st January 2016 to 30th April 2019. This is estimated to be around 300 individuals.

The identification of the cohort will be undertaken by the research team at HM Prison and Probation Service and is outside of the scope of this application. The applicants will be provided with the following information:

- Identification number,
- Prisoner name,
- Establishment,
- Date of death,
- Prison number.

This information will be provided to the Healthcare Manager at the prison where the individual died in order for information to be collated from the individual's medical record (within the scope of support). The questionnaire containing information from the medical record will be returned to the applicants.

Confidentiality Advisory Group advice

Public Interest

Members were assured that the application defined a medical purpose which 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 CAG acknowledged that consent was not feasible for the project as the patient cohort in question was deceased.

- Use of anonymised/pseudonymised data

The applicants were not directly processing any confidential patient information as part of the application activity; however, due to the personal information which was held by the applicants, the healthcare information returned about the patient cohort would be potentially identifiable.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. Members were assured that the information requested was appropriate to the application activity proposed.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicants had requested cover under the Regulations up to 31 December 2019, to enable the study analysis to be undertaken.

Dissemination of Research Findings

The CAG requested further information around the dissemination plans of the research findings, as it was acknowledged that the outcomes of the project would be of wider interest outside the field of academic research. Clarification would be sought from the applicants.

Patient and Public Involvement and Engagement

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

Members acknowledged that the content of the questionnaires had been informed by a previous study in this area and also involvement with service user groups. The Group was assured that the engagement activity which had been undertaken was relevant and appropriate to the proposed application.

Patient Notification and Dissent

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

The Group recognised that a patient notification and dissent mechanism could not be operated for a deceased patient cohort in the standard manner. Members were assured by the applicant's intention to check the patient's records for historical dissent. It was also noted that the applicants would be publishing information on the Offender Health Research Network's website.

Members queried whether there was potential to draw the research project to the attention of the Coroners' service, to enable it to be raised where appropriate with the families of deceased patients. A recommendation would be made to the applicants to explore the feasibility of the option and provide feedback at the time of first annual review.

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. Provide further information around dissemination plans for the research findings.

Specific Conditions of Support (Provisional)

1. Explore the potential of linking with the Coroners' Service to enable the project to be raised with the families of deceased patients. A report should be provided at the time of first annual review around the work undertaken here.

2. Favourable opinion from a Research Ethics Committee. **(Confirmed – 20 September 2017).**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – University of Manchester – Offender Health Research Network shows a reviewed grade of 83% satisfactory on Version 14, 2016/17).**

6. MINUTES OF THE MEETING HELD ON 24 AUGUST 2017

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

7. CAT OFFICE REPORT

CAG Away Day – Overview

Members were reminded that the next CAG Away Day is scheduled for Wednesday 11 October 2017, 10.30am – 4.15pm

A draft agenda was shared with the Group for consideration, together with some logistical details around travel and accommodation requests.

CAG Research Stakeholder Event – February 2018

Further to the success of the CAG Patient and Public and Key Stakeholder event which was held in February 2016, work has begun to plan a similar event for this financial year.

It has been agreed that the event will take in February 2018 and will be held in the Manchester area. The focus of this year's event is around research stakeholders.

Initial planning has begun within the Chair team, with Dr Tony Calland taking the lead on the event. Ms Rachel Heron will be leading on the event from the CAT perspective, with support from the wider team.

CAG Minutes – August 2017

Minutes of the CAG business undertaken in August 2017 were shared for information purposes. This included the full CAG meeting on 24 August 2017, Precedent Set Sub-Committee and standard Sub-Committee business.

Expense Claims

Members were reminded of the importance of submitting expense claims in a timely fashion for expenses incurred in connection with CAG business. Submission details were provided together with a copy of the relevant expenses claim form.

8. CAG CHAIR REPORT

The Chair's Report for September 2017 was circulated ahead of the meeting. Members received the report and no issues were raised.

9. ANY OTHER BUSINESS

The Chair raised a query with Members present seeking examples of research projects which utilised data which had been collected without research as its primary aim. It was agreed that feedback would be provided direct to the Chair.

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