NHS
Health Research Authority

# Minutes of the meeting of the Confidentiality Advisory Group

## 26 October 2017 at Barlow House, M1 3DZ

**Group Members:**

| *Name* | *Present* | *Notes* |
|---|---|---|
| Dr Malcolm Booth | Yes | |
| Ms Sophie Brannan | Yes | Lay |
| Professor Barry Evans | Yes | |
| Mr Anthony Kane | Yes | Lay |
| Ms Kim Kingan | No | Apologies received |
| Dr Rachel Knowles | Yes | |
| Mr Andrew Melville | Yes | Lay |
| Mrs Diana Robbins | Yes | Lay |
| Ms Clare Sanderson | Yes | Alternate Vice Chair |
| Dr Mark Taylor | Yes | Chair |

**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.d – Ms Clare Sanderson advised that she has previously worked with IMS Health; however, she confirmed that she had been involved in this application submission or any of the individuals named on the project. The CAG agreed that this did not constitute a true conflict of interest and no action was required.

- Agenda Item 5.d – Dr Malcolm Booth advised that he had been involved as Chair of the corresponding REC review of the application. It was acknowledged that Dr Booth was not assigned as part of the reviewing team for this item. The CAG agreed that this did not constitute a true conflict of interest and no action was required.

## 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. Researcher Stakeholder Engagement Event

The Chair referred Members to a circulation which had been made by the Head of the Confidentiality Advice Service which explained that a decision had been taken to postpone the Researcher Engagement Event which it was intended to take place in February 2018.

## 4. AMENDMENTS

### a. 16/CAG/0038 – Risk Stratification tools to identify patients with advanced COPD

**Context**

Purpose of Application

This application from University Hospitals of Leicester NHS Trust set out the purpose of investigating which measurements best assess the severity of Chronic Obstructive Pulmonary Disorder (COPD), and how best to use these measurements to determine how many patients have advanced disease.

The project will use health data about patients with COPD that is already recorded by GP practices in Leicester, Leicestershire, and Rutland (LLR) and which is being used to help local health organisations work out the health needs of the local population. This information cannot be used to identify an individual

patient by the research team. The researchers will use this information to find out how many patients with advanced COPD are living in LLR and how best to predict their future needs for healthcare.

Background to Existing Application

The applicant asserted that the previous information sharing arrangements permitted the Arden and Greater East Midlands Commissioning Support Unit (Arden and GEM CSU) to receive patient level data from LLR practice read codes via clinical system suppliers. Patient identifiable information is placed in an accredited secured data safe haven (within Arden and GEM CSU) where it is pseudonymised immediately upon receipt. This data is then linked to pseudonymised data from other NHS information systems (Secondary Uses Service (SUS)) using the NHS number as the unique identifier.

The legal basis for this information sharing and linking of datasets as specified above was stated to be established by NHS England under reference CAG 7-04(a)/2013. This application allowed disclosure of commissioning data sets (SUS) from NHS Digital and the disclosure of data from GP systems to a data processor (Arden and GEM CSU) working under the instruction of GPs as data controllers, to enable the preliminary processing and linkage of the data, for the non-research purpose of risk stratification.

Confidential Patient Information Requested

Support was requested to cover the disclosure of identifiable data from patient level data from GP practices within the LLR regions to Arden and GEM CSU for the additional purpose of research. The following additional data items will also be collected (not currently included in the data flow specified under CAG 7-04(a) 2013:

1. FEV1 (in L and % predicted), MRC (Medical Research Council) dyspnoea score,
2. BMI (Body Mass Index),
3. Home oxygen use,
4. Exacerbations in the preceding 12 months,
5. Prescriptions of antibiotics and steroids for exacerbations and of maintenance medications for COPD,
6. Smoking status.

The recipient would not receive an identifiable dataset; however, support was requested to enable the processing of the already held dataset to enable the de-identified dataset to be provided to the research team, for the purpose of research.

**Amendment Application**

Background

Arden and GEM CSU is no longer providing risk stratification services for the LLR CCGs, following a competitive tendering processing, which it did not win. As Arden and GEM CSU is no longer the data processor for the risk stratification activities covered under the non-research application CAG 7-04(a)/2013, which was submitted by NHS England, support is required for them to receive the data specifically for the purposes of this research project. Primary care data would need to be provided direct to Arden and GEM CSU from GPs in the area.

The additional data required from the SUS dataset, held by NHS Digital, would no longer be provided to Arden and GEM CSU under the CAG 7-04(a)/2013 application, as they are no longer the data processor for the standard risk stratification activities.

Amendment Request

This amendment seeks support to allow University Hospitals of Leicester to make an application to NHS Digital, for the required pseudonymised SUS data to be shared direct with Arden and GEM CSU on their behalf, to enable the proposed data linkage to be undertaken. Primary care data would continue to be

supplied to Arden and GEM CSU by GPs in the same format and method as set out in the original proposal, so there would be no change to these data flows.

There is no change to the study purpose, methodology or benefits. The current approval permits the research study team to receive pseudonymised level risk stratification output along with specific COPD related data fields and there is no change to this either. The research study team will still receive pseudonymised record level data, as per original application and approval.

The applicants stated that the amendment would also require a change to the data controllership arrangements for the project from LLR (Leicester, Leicestershire, and Rutland) CCGs to University Hospitals of Leicester NHS Trust.

**Confidentiality Advisory Group Advice**

The amendment requested was initially considered by the Chair under a Chair's Action; however, it was agreed that due to the content of the amendment, it was more appropriate to escalate this amendment for review by a full complement of Members at a CAG meeting. The rationale for the escalation was identified as, if a recommendation of support was given to the amendment, there was potential that flows of confidential patient information would be duplicated for differing purposes.

The Group recognised that it would not be usual practice to provide a recommendation of support for an activity which may involve the duplication of data processing; however, it was identified that there were exceptional circumstances within this application. Members acknowledged that the activity had already commenced and a pilot study had been undertaken and the importance of the main study proceeding with the same tools and the experience gained from this process was accepted. It was explained that the new provider of risk stratification services to Leicester, Leicestershire and Rutland CCGs was not yet fully mobilised so there was currently no possibility of the project transferring to the new provider. The CAG was sympathetic to the situation as the change to the risk stratification service provider was not within the control of the research applicants; however, there was potential that the work undertaken to this point could be penalised because of this. The Group further commented that as it had provided a recommendation of support for this research activity to take place upon submission of the initial application, it remained supportive of this continuing. If the applicants were unable to complete the project which they had begun, it was remarked that the processing of confidential patient information which had been undertaken to this point would have done so without purpose.

It was advised that Arden and GEM CSU was still contracted to provide risk stratification services for other CCGs. The CAG took assurance that the proposed data processor was continuing to provide the risk stratification services, though not to the specific CCG region involved with this research project.

Arden and GEM CSU had provided written assurance that any data received for the purposes of this project would not be used by themselves in any format, including fully anonymised, for any other purpose. It was further clarified that all data pertaining to this project would be destroyed by Arden and GEM CSU at that point at which the research team confirmed receipt. The CAG took assurance in these clarifications that Arden and GEM CSU, as data processor, would not make wider use of the data disclosed to them for the purposes of this research project. Members agreed that this should be added as a specific condition to the recommendation of support to clearly articulate the limitations on Arden and GEM CSUs continued involvement with this project.

It was explained that there were time and resource limitations on this project, which it was clarified, must be completed by December 2018. The Group discussed these limitations and it was observed that had the project not yet commenced or be in the early stages of a lengthy proposal, the request may have been viewed differently.

It was advised that the CCG Research and Development Lead for the three CCGs confirmed on 13 September 2017 that a letter (from the three CCGs) expressing support for the study would be issued. The intended purpose of the letter was to make it available to each GP so they are informed of the support of

the CCGs from a research and development perspective for the project. The letter will be sent to each General Practice at the time they are invited to participate in the research study and asked to sign a data sharing agreement with University Hospitals of Leicester NHS Foundation Trust. Members were assured that each individual GP practice was able to determine their continued involvement with the research project. It was further acknowledged that there had been initial engagement with the local LMC which would be assisting in further targeted engagement with GPs. The Group took further assurance from the continued support for the project from the local LMC.

The CAG considered the data controllership arrangements for the project as it was recognised that the amendment request had suggested that the CCGs had previously been the data controller for the research activity and this was now required to be University Hospitals of Leicester NHS Trust. Members commented that, from the information set out in the original application and associated outcome letters, it had been understood that University Hospitals of Leicester NHS Trust had been data controller for this research application from the outset, as it was this organisation which had determined the manner and purpose of the data processing in relation to the research proposal. It was acknowledged that the GPs by way of the CCGs were data controllers for the overall risk stratification programme which was covered under the non-research application CAG 7-04(a)/2013.

It was understood that, as they were no longer the contracted risk stratification service provider on behalf of the LLR CCGs, Arden and GEM CSU would no longer receive the pseudonymised SUS data from NHS Digital. Members acknowledged that the applicants, University Hospitals of Leicester, were making a separate application to NHS Digital to request the release of the pseudonymised data to Arden and GEM CSU, acting as data processor on their behalf, to enable linkage with the pseudonymised primary care data which will be shared directly with Arden and GEM CSU, on behalf of University Hospitals of Leicester NHS Trust. Support for this data flow was recommended.

**Confidentiality Advisory Group Conclusion**

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

**Specific Conditions of Support**

1. Support extends to the disclosure of primary care data to Arden and GEM CSU from GP practices with the LLR CCG areas that confirm ongoing support for the project by signing an individual data sharing agreement.
2. Support extends to the disclosure of pseudonymised SUS commissioning data from NHS Digital to Arden and GEM CSU, on behalf of University Hospitals of Leicester NHS Trust, for the research purposes set out in this application.
3. Support extends to Arden and GEM CSU, as continuing data processor for this specific project, will undertake the necessary data processing as set out in this application.
4. Arden and GEM CSU will not use the data provided to them for the purposes of this project, in any format, for any other purpose than those set out in this application.
5. Arden and GEM CSU will destroy all data which was disclosed to them for the purpose of this project at the point the research team confirms receipt of the linked pseudonymised dataset.
6. Support extends to 31 December 2018 only – as per the end date confirmed by the applicants.
7. Confirmation of suitable security arrangements via IG Toolkit submission. **(PENDING).**
8. Confirmation of a favourable opinion from a Research Ethics Committee. **(Non-Substantial Amendment for REC purposes, submitted 18/08/2017 – no approval required).**

**5. NEW APPLICATIONS – Research**

**a. 17/CAG/0173 – UK MedEye**

**Context**

Purpose of application

This application from Newcastle University sets out the purpose of medical research into the use of MedEye, a bedside tool used to prevent medication administration errors. The system scans medication at the bedside and verifies whether the correct medication is being administered. The combination of MedEye technology with an electronic health record (EHR) and prescribing system holds a great deal of promise to reduce medication errors at the administration stage for hospitalised patients. However, without evidence on safety, effectiveness and efficiency, it is difficult for health care organisations to prioritize this technology among many other potential safety interventions.

The study contains a number of elements; however, the CAG consideration is only in relation to the first aim of the project, which is to evaluate what effect the MedEye system has on the incidence of serious medication administration errors. Two research observers will undertake observation of medication administration in the wards 2-4 weeks prior to the roll out of MedEye and then 4-8 weeks afterwards. The observers will be clinically experienced healthcare professionals who hold an honorary contract with the Trust. They will be blinded to the clinician's prescribing instructions. Support is requested to allow the researcher observers to access the medical records of the patients whose medication administrations were observed to check the accuracy of drugs administered against those prescribed.

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

Confidential Patient Information Requested

Cohort

All patients aged over 18 years admitted to adult wards during the study period will be eligible to be indirectly involved in the study. 16 wards will be included in the study which will be half surgical and half medical.

Each single tablet administration which is observed is classed as one observation. It is intended that 16,000 medication administrations will be observed in total. Intravenously administered and solution based medications are excluded from the project.

The following items of confidential patient information will be accessed and utilised for the purposes described:

- Patient name – validation,
- NHS ID Number – validation,
- Date of Birth – accessed to enable patient age to be recorded – analysis,
- Gender – analysis,
- Ethnicity – analysis.

Further clinical details in relation to the patient's prescription will also be required.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG was assured that the study described a medical purpose through medical research which it agreed was in the public interest, due to the risks involved with drug administration errors. The Group agreed there was potential for patient benefit if the Med-Eye technology being evaluated was found to be effective.

Practicable Alternatives

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

- Feasibility of consent

The applicants had stated in response to queries that the focus of the observation was the nurses, rather than the patients who were deemed not to be directly involved in the study. Members raised some concerns around this point as it was understood that the researcher observers would not only be observing the patient's drug administration but also taking information from the patients' notes to facilitate the accuracy check against prescriptions within medical records. The potential difficulties which the applicants had identified in seeking consent from patients who were potentially unwell were acknowledged by Members; however, it was commented that this in itself was not a strong enough justification against seeking consent. The Group commented that the use of confidential patient information was integral to the study and further consideration was required by the applicants to provide a stronger rationale to support why patients could not be consented for the use of their data.

- Use of anonymised/pseudonymised data

The Group was assured that access to confidential patient information was required to enable the accuracy of drug administrations to be confirmed against the patient's medical record.

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 unclear why gender and ethnicity were required as part of the analysis dataset – clarification around these items had not been provided within the application. Members agreed that justification would be required from the applicants to support these data items as it was unclear what relevance these had to the project analysis.

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. Whilst study analysis was being undertaken on a pseudonymised dataset, the applicants state that capacity to link back to patient's records was required in case any data integrity issues were raised. Support was requested for the duration of the study with an additional three month period for data integrity issues. The CAG was assured that access to confidential patient information had been limited and was supportive of the extended retention of the pseudonymisation key.

Patient and Public Involvement and Engagement

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

The applicants identified that there had been no public or patient involvement or engagement activity undertaken to date within the project; however, plans had been set out to link with Newcastle University's Engagement and Impact Team in order to develop a plan for working with patients and/or the public. Members were in agreement that engagement activity would need to be undertaken prior to any recommendation of support being provided, to enable the acceptability of using confidential patient information without consent to be tested. Feedback would need to be provided around the activity which had been carried out. If the responses given were negative, the CAG would take this into account when

considering whether a recommendation of support can be given to the activity, or whether further actions are necessary.

Patient Notification and Dissent

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

Members considered the poster which had been provided as a patient notification mechanism. It was commented that the document did not advise that confidential patient information was required as part of the project, or that medical records would be accessed. It was agreed that, should a recommendation of support be considered for the application, significant revisions would be required to the document. The poster would need to clearly explain what the project involved for patients, explain that there was the right to raise an objection and an alternative means of contact would need to be provided as it was commented that access to email would be limited for many inpatients. It was suggested that it may be appropriate to display the poster more widely within the hospital, rather than just on the wards involved.

The Group suggested that further communications would be required to supplement the poster, which could include an information leaflet which could be passed to patients within the ward or include brief face to face discussions. The CAG agreed that further work would need to be undertaken around the communications strategy if a recommendation of support was to be provided. It was agreed this could be discussed as part of any patient and public engagement activity which was arranged in order to inform any plans which were devised for the project.

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. Confirmation of the favourable ethical opinion would be required before any recommendation of support can be provided.

**Confidentiality Advisory Group Advice Conclusion**

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

**Request for Further Information**

1. Further information is required to explain why seeking consent from patients for the use of their data within the project is not feasible.
2. Justification is required to explain why gender and ethnicity are required for the study analysis.
3. Patient and Public Involvement and Engagement – activity should be undertaken in this area and feedback provided to the CAG for consideration. The following points should be addressed:

a. The acceptability of using confidential patient information without consent for the proposed application activity should be tested. If the responses provided are negative, the CAG will take this into account when considering whether a recommendation of support under the Regulations should be made.
b. Patients and the public should also be engaged with around the communications strategy for the project to seek views on how it could be best promoted together with review of any materials.

4. Patient Notifications and Dissent – the information materials used to inform patients and the public of the application activity and offer a means objection require revision. The following points should be considered:

a. The poster requires revision to address the following points:
   i. Include clear information around what the project involves, explaining how and why data will be accessed,
   ii. It should be explained that patients have the right to raise an objection to the use of their data and explain how this can be done,
   iii. Alternate means of contact should be provided to supplement the email addresses which are detailed within the document,
   iv. It was noted that one of the email addresses detailed within the text included a typographical error.
b. Additional communication strategies to promote the project are required to supplement the poster. A detailed overview should be provided, together with copies of any documentation for consideration by the CAG.

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

**Specific Conditions of Support (Provisional)**

1. Favourable opinion from a Research Ethics Committee. **(Pending).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – Newcastle upon Tyne Hospitals NHS Foundation Trust shows a reviewed grade of 92% satisfactory on Version 14, 2016-17).**

**b. 17/CAG/0176 – UK-COMPASS**

**Context**

Purpose of Application

This application from the Royal Liverpool and Broadgreen University Hospitals NHS Trust set out the purpose of medical research to examine how the different treatments for abdominal aortic aneurysm compare in terms of clinical benefit and the utilisation of NHS resources. The applicants intend to analyse the outcomes of all patients undergoing juxtarenal aneurysm treatment in England without altering their treatment, during a two-year period with collection of follow-up data over a five year period. The applicants will examine routinely performed scans and utilise data that is routinely collected by the NHS. Available data will be analysed to compare the safety and effectiveness of different treatments and to see if a particular treatment is better suited for particular features so patients can be offered bespoke treatment strategies. The project does include a consented PROMS element which is out of scope for CAG consideration.

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

Confidential Patient Information Requested

Cohort

Male and female patients aged between 25 – 100 years undergoing elective juxtarenal abdominal aortic aneurysm repair in England; juxtarenal abdominal aortic aneurysm defined and stratified into 4 strata of anatomical complexity as specified in 'Anatomical and Physiological Stratification' or those with a juxtarenal

abdominal aortic aneurysm 55mm or larger in size and placed on medical management 'operation-deferred'.

Patients treated from November 2017 to October 2019 will be screened retrospectively for inclusion. It is expected that confidential patient information in relation to approximately 8000 patients would be screened over the two year recruitment period to identify approximately 2000 patients with complex aneurysm repair for inclusion in the analysis. Interim analysis will be undertaken at 12 months to verify our estimates of sample size and power.

NHS Digital will retrieve data from HES and supply to the research team at the Royal Liverpool and Broadgreen Hospitals NHS Foundation Trust on a two monthly basis. This will include the following data items:

- NHS number – Validation and linkage,
- Date of birth – Validation and linkage,
- HES-ID – provided in a pseudonymised format to allow data linkage.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG was assured that the application described a medical purpose through medical research, which was in the public interest, by gaining an improved understanding of the care pathways for this patient cohort.

Practicable Alternatives

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

- Feasibility of consent

The applicants provided a comprehensive rationale to support why consent was not feasible for the project, including both scientific and practical reasons, which included the requirement for complete ascertainment, potential to increase bias due to research-active hospitals being the only sites able to recruit and the potential for some of the patient population to be deceased. The applicants had undertaken preparatory work with the NIHR-HTA Commissioning Board which had surmised that a randomised-controlled trial was not feasible for the project. The CAG considered the rationale which had been provided and was assured that consent was not feasible for the project.

- Use of anonymised/pseudonymised data

Members were satisfied that processing of confidential patient information was required to enable the establishment of the patient cohort and to facilitate linkage with wider datasets.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. The CAG was assured that the identifiers requested were appropriate for 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 CAG acknowledged the work which had been undertaken to limit the access and processing of confidential patient information within the project. Members were unclear from the detail provided within the application what the proposed retention periods were for each of the numbered datasets within the dataflow chart. It was agreed that clarification would be required from the applicants around this, to ensure that any recommendation of support was extended for the appropriate duration.

The Group understood that support under the Regulations would need to continue for the duration of the project to provide a legal basis for the data processing which would be undertaken by NHS Digital. The CAG was content to extend the recommendation of support to this ongoing processing for follow-up of the patient cohort.

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 there had been strong public and patient engagement and involvement undertaken in the planning of the project which was commended. The applicants had explained that there would be one PPI representative included in the trial steering group as the project progressed. The Group commented that this could be improved through involvement and engagement with a wider representation of public and the patients. This requirement would be added as a condition of support, with a report required at the time of first annual review around the actual activity which was undertaken as the project commenced.

Patient Notification and Dissent

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

The CAG agreed that the patient information poster which had been prepared to facilitate a patient notification and dissent mechanism was clear and informative; however, it was noted that the data processed in the study was referenced as anonymous, which was not technically accurate. It was also noted that the option of objection was referenced as an opt-out. It was recommended that these two points were revised within the document. Members commended the various means of contact which had been provided within the poster to allow a patient to raise an objection or contact for further information.

It was suggested that an information leaflet could be produced which included further detail about the project for those patients who requested additional information. The CAG advised that the public and patient group which had been involved in the design phase of the project should be approached to assist with the drafting of this document.

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. Confirmation would be required that a favourable ethical opinion is in place for the project before any recommendation of support would come 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. Clarify the retention periods for each of the datasets which would be established within the study.

Recommendation:

1. It was recommended that minor revisions are made to the study poster to address the following points:
   a. Accurately reflect that confidential patient information would be processed during the project, without patient consent,
   b. Revise the reference to opt-out to raising an objection to the use of data.

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

**Specific Conditions of Support (Provisional)**

1. Support extends to England and Wales only.
2. Patient and Public Involvement and Engagement – further activity should be planned and undertaken to progress public and patient involvement and engagement as the study commenced. It was acknowledged that this should be extended to more than one PPI representative within the Trial Steering Group. A report would be required at the time of first annual review to describe the wider additional activity which had been undertaken in this area.
3. Patient Notifications and Dissent – it is recommended that a supplementary patient information leaflet is drafted to be provided to those patients who contact the team to request further information about the study. It was recommended that the patient and public representative group are involved with the preparation and review of this document. Submission of the document would be required at the time of first annual review together with an overview of how it was prepared.
4. Favourable opinion from a Research Ethics Committee. **(Pending).**
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – Royal Liverpool and Broadgreen University Hospitals NHS Trust shows a reviewed grade of 84% satisfactory on Version 14 (2016/17). NHS Digital shows a reviewed reported grade of 92% satisfactory on Version 14 (2016/17).**

**c. 17/CAG/0177 – Exploring DNA Methylation as an Initiating Event in Childhood Cancer**

**Context**

Purpose of Application

This application from Newcastle University sets out the purpose of medical research to investigate whether DNA methylation is an early event in childhood cancer. Cancer is caused by a series of abnormal genetic and epigenetic events. To investigate if abnormal DNA methylation is an early event in childhood cancer development, the applicants will compare methylation patterns of childhood cancer patients and healthy controls in previously collected blood spots taken 5-8 days after birth (i.e. before diagnosis in the cancer patients).

The Great North Biobank houses blood spots collected from neonates 5-8 days after birth between the years 1984-1994 in the local region. The Northern Region Young Persons' Malignant Disease Registry (NRYPMDR) is a specialist population-based registry of all childhood and young adult malignancies diagnosed since 1968 in the northern region of England.

Using the NRYPMDR, the applicants will identify cases and access the neonatal blood spot card corresponding to individual cases from the Great North Biobank. Upon accessing cases, age and sex matched control blood spot samples will be selected. Name, date of birth and NHS number data will be used to confirm that selected controls were not on the NRYPMDR. Once cases and controls have been selected, blood spot samples will be assigned an identification number so that data can be anonymised, removing name, NHS number and day of birth. Use of the blood spot samples is out of the CAG remit; however, the associated data processing is what required a recommendation of support.

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

Confidential Patient Information Requested

Cohort

Female and male patients up to the age of 25 years, with a new born blood spot taken between 1984 and 1994 will be included in the study. Cases will be selected based on cancer type and availability of neonatal blood spot in the biobank. Controls will be selected to match cases based on sex and closest date of birth.

60 cases will be recruited in total (30 patients and 30 control cases).

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

- Name – to enable correct sample to be retrieved from the biobank and validating control samples,
- NHS number – sample collection and validating control samples,
- Date of birth – sample collection, control sample matching and validation,
- Sex – control sample matching.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG was assured that the application defined a medical purpose through medical research which was within the public interest, as it aimed to gain a greater understanding of childhood cancers in order to facilitate the development of new treatments and improve patient care.

Practicable Alternatives

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

- Feasibility of consent

Members were satisfied that consent was not feasible for the cohort to be included in the project due to the retrospective nature of the samples and the potential for patients to be deceased.

- Use of anonymised/pseudonymised data

The Group was assured that the project could not proceed without processing confidential patient information as this facilitated linking data from the cancer patient cohort to their corresponding blood spot sample within the biobank and matching to the control cohort.

Justification of Identifiers

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

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. It was identified that the applicants were only processing confidential patient information to facilitate cohort validation and the retrieval of the relevant blood spot samples, following which, data would be anonymised. The CAG was assured that an appropriate exit strategy from the requirement for support had been established.

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 engaging with the Voice North patient group around the project. Whilst Members recognised that the engagement with Voice North was a positive action, it was identified from the website that the specific focus of the group was ageing. It was agreed that further engagement was required with a more appropriate patient and public group to seek their views on the proposal. Members suggested that parents of an infant with cancer or adult patients who had suffered cancer as a child were both suitable options. It was agreed that the feedback from this interaction, together with the Voice North group, would need to be considered before any recommendation of support for the activity could be provided. If the responses given were negative, the CAG would take this into account when considering whether support for the project should be recommended, or whether further actions are necessary.

Patient Notification and Dissent

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

The Group acknowledged that information would be displayed on both the University website and also that of Voice North in order to promote the project to the public. It was commented that the information within the notifications was fairly complex and may not be understood by a layperson.

Members discussed the suitability of the communication strategy and it was recognised that the proposal was for a feasibility study with a limited cohort. The CAG agreed that the proposed system was adequate in these circumstances. The Group discussed the potential for a future wider study to be undertaken in follow-up to this. It was commented that, whilst the patient cohort included in the study would be aware of their inclusion in the malignant disease registry, it was unlikely that those whose data was accessed in order to create the control cohort would identify with the project. Members agreed that if a further follow-up project was undertaken, a wider and more comprehensive communications strategy would be required to support the application, particularly requiring clear information to be posted on the websites of all organisations involved with the project.

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. Confirmation of a favourable ethical opinion would be required from 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. Patient and Public Involvement and Engagement – further information is required in this area to address the following points:
   a. Feedback from the presentation to the Voice North group should be provided for consideration,
   b. Further engagement activity should be undertaken with an appropriate patient group to test the acceptability of the use of confidential patient information without consent as described in the application,
   c. An overview would be required around the additional patient/public group which had been engaged with, together with any feedback provided,
   d. It was suggested that this additional engagement activity could take the form of a focus group/discussion,
   e. If the feedback which is provided is negative, the CAG will take this into account when considering whether a recommendation of support should be given to the proposal.

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

**Specific Conditions of Support (Provisional)**

1. Favourable opinion from a Research Ethics Committee. **(Pending).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – a project specific IGTK has been submitted under reference EE133852- DNA Methylation – this shows a reviewed satisfactory grade of 66% on Version 14 (2016-17).**

**d. 17/CAG/0179 – Epidemiologic study of surgical site infections (SSI) following hip and knee replacement procedures in European countries**

**Context**

Purpose of Application

This study from the Hampshire Hospitals NHS Foundation Trust set out the purpose of medical research into surgical sites infections in patients who underwent hip and/or knee arthroplasty procedures between July 2013 and June 2015 at approximately 5-10 hospitals in Europe. This is a retrospective cohort of all hip/knee arthroplasty procedures performed during that time frame with a nested case-control analysis of all SSIs occurring after those procedures. Surgical sites infections rates for S. aureus, including methicillin-

resistant (MRSA) and methicillin-susceptible Staphylococcus aureus (MSSA), as well as other pathogens will be described.

Medical record review will be performed to collect limited data on the cohort as a whole, with more detailed relevant data collection to be done on surgical sites infections cases and uninfected controls. This design will enable calculation of procedure-specific incidence rates, comparisons between S. aureus surgical sites infections cases and controls, and description of SSIs in this surgical population. The retrospective data collection is planned to start in Jun 2017 and end in Apr 2018.

The data collection is being undertaken by members of the direct care team. A participant identification log will be held on site; however, the study analysis is being undertaken on a de-identified dataset. The study is being undertaken on an unconsented basis. The actual study activity does not require support under the Regulations as there is no breach of the common law duty of confidentiality as data extraction is being undertaken by the direct care team only. The element which is being put before the CAG is around the potential for individuals performing source data verifications, monitoring or audit/inspection to ensure that the study has been conducted correctly requiring access to confidential patient information through checking against patient records.

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

Confidential Patient Information Requested

Cohort

All patients who underwent a primary or revisional hip or knee replacement procedure, between 1 July 2013 and 30 June 2015, at the study sites. No age restrictions apply. Two cohorts will be defined – a case cohort of patients with culture-confirmed site-specific infection and a matched control cohort without infection at an inclusion ratio of 1:2.

The following details will be recorded to enable the de-identified analysis dataset to be traced back to patient recorded to enable the data to be verified.

- Name – verification,
- NHS number – verification,
- Hospital Number – verification,
- Date of birth – verification,
- Date of death – verification,
- Gender – verification,
- Postcode – verification,
- Ethnicity – verification,
- Age at time of surgery – analysis,
- Date of discontinuation – analysis.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG acknowledged that the overall study identified a medical purpose through medical research which was in the public interest as it intended to gain a greater understanding of surgical site infections.

Practicable Alternatives

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

- Feasibility of consent

Members were assured that consenting was not a feasible alternative for the project due to the potential to include bias to the study and that due to the period of time since the procedures were undertaken, some patients could be lost to follow-up or deceased.

- Use of anonymised/pseudonymised data

The applicants had identified that the project analysis would be undertaken on an anonymised dataset which had been extracted by the direct care team. It was recognised that by designing the study in such a manner, the applicants had avoided causing a breach of the common law duty of confidentiality. The application submission had been made to the CAG in order to seek support for a data verification programme which may be undertaken in order to test the integrity of the data which had been extracted from patient records. Members suggested that this activity could potentially be undertaken by a wider member of the direct care team that had not been involved in the data extraction or on a copy of the notes from which patient identifiers had been redacted. It was not apparent from the detail provided within the application whether these practicable alternatives to seeking support under the Regulations had been considered by the applicants. The CAG agreed that, should the applicants consider making a resubmission for further consideration, clear explanation would be required to explain why the proposed methodology was the only means of maintaining data integrity.

The Group considered the particulars of the request and it was agreed that the prospective list of individuals and organisations which may potentially require access to a patient's medical record in order to undertake this audit activity was wide reaching and non-specific. It was commented that, when considering a recommendation of support under the Regulations, specific articulation was required around how and when a breach of the common law duty of confidentiality was occurring together with detail around who or which organisation would access the data. The CAG stated that the request which had been received did not provide the granular detail which was necessary in order for a recommendation of support to be considered. It was agreed that, should a resubmission of the proposal be made, this would need to be much more detailed, explaining precisely which individuals or organisations would require access to patient records (rather than a potential list) at what stage of the project and for what purpose. Members agreed that without this narrowed and defined scope, an informed consideration could not be undertaken of the practicable alternatives which appeared to exist.

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 agreed that if a resubmission of the application was made, a clear overview of patient identifiers which were required to facilitate the data validation would be required.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The applicants had not undertaken any public or patient engagement within the project design and this was not planned as the project progressed. It was acknowledged that it was standard practice for applicants to test the acceptability of using confidential patient information without consent with patients and the public to support the public interest in an application activity. Feedback from activity in this area would be required as part of any resubmission. If the responses given were negative, the CAG would take this into account when considering whether support could be recommended for the activity, or whether further actions are necessary.

Patient Notification and Dissent

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

The applicants had not described any communication strategy to inform patients and the public of the proposed activity or offer a means to enable objection to be raised. The CAG agreed that, should a resubmission be made, the applicants would need to make provisions for a patient notification system which should allow the option of objection.

**Confidentiality Advisory Group Advice Conclusion**

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met, and therefore advised that the application was not supported.

## 6. MINUTES OF THE MEETING HELD ON 28 SEPTEMBER 2017

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

## 7. CAG CHAIR REPORT

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

## 8. EDUCATIONAL ITEMS

The CAG discussed the future educational items schedule and suggestions were noted to be taken forward by the Confidentiality Advice Team on behalf of the Group.

## 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.