Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

07 June 2018 at 10:00am at Skipton House, SE1 6LH

Present:

Name	*Present*	*Notes*
Ms Sophie Brannan	Yes	Lay
Dr Tony Calland MBE	Yes	Chair
Dr Patrick Coyle	Yes	Vice-Chair
Dr Liliane Field	Yes	
Dr Rachel Knowles	Yes	
Dr Simon Kolstoe	Yes	
Mr Andrew Melville	Yes	Lay
Mrs Diana Robbins	Yes	Lay
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Miss Kathryn Murray	Senior Confidentiality Advisor
Ms Amanda Hunn	Observer – HRA Joint Head of Policy
Dame Fiona Caldicott (Agenda Item 3 only)	National Data Guardian
Ms Jenny Westaway (Agenda Item 3 only)	Head of the Office of National Data Guardian
Ms Juliet Tizzard (Agenda Item 3 only)	HRA Director of Policy

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introductions

Dr Liliane Field, newly appointed CAG Member, was welcomed by the Chair to her first CAG meeting.

Ms Amanda Hunn, HRA Joint Head of Policy, was welcomed to the meeting. It was explained that Ms Hunn would be taking over responsibility as the nominated decision-maker on behalf of the HRA and was observing in this capacity.

Dame Fiona Caldicott, National Data Guardian, and Ms Jenny Westaway, Head of the Office of the National Data Guardian, were welcomed to the meeting for agenda item 3 only. Dr Juliet Tizaard, HRA Director of Policy, was also in attendance for this agenda item.

Apologies for Absence

Apologies were received from Dr Lorna Fraser

Declarations of Interest

The following interests were declared:

Agenda Item 4.a: 18/CAG/0091

Dr Lorna Fraser confirmed in advance of the meeting that she was a Co-Investigator on the wider Connected Yorkshire programme and could not be part of the application review. Dr Fraser submitted apologies for the CAG meeting; however, it was agreed that as this was a true declaration of interest, this should be recorded in the minutes.

The CAG noted that Ms Clare Sanderson, CAG Alternate-Vice Chair, had been involved in the initial submission of this application (17/CAG/0178). Whilst no formal involvement had been notified as part of the revised application, the Group agreed that this historic declaration of interest should be carried forward in the minutes.

Agenda Item 5.a: 18/CAG/0090

Dr Patrick Coyle, Vice Chair, advised that he was previously the Medical Director for the Abertawe Bro Morgannwg Health Board, which was the applying organisation for this proposal. It was acknowledged that some years had passed since Dr Coyle held this position and he had no involvement in the application. The CAG agreed that this was not a true declaration of interest and did not require any action; however, this would be noted in the minutes for transparency.

Agenda Item 5.c: 18/CAG/0100

Mr Marc Taylor, CAG Member, advised that he previously used to sit on a Board with Professor Rory Collins, the Information Guardian named on this application. The CAG agreed that, as some years has passed since Mr Taylor's interaction with Professor Collins, this was not a true declaration and did not require further action; however, this would be noted in the minutes for transparency.

2. APPROVAL DECISIONS

Secretary of State for Health and Social Care Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health and Social Care (SofS) agreed with the advice provided by the CAG in relation to the 05 April 2018 meeting applications.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 05 April 2018 meeting applications.

3. CONSIDERATION ITEMS

a. Presentation by the National Data Guardian – to be led by Dame Fiona Caldicott

Dame Fiona Caldicott, National Data Guardian, and Ms Jenny Westaway, Head of the Office of the National Data Guardian, were in attendance to lead the Group through a presentation.

The Chair thanked Dame Caldicott and Ms Westaway for their attendance and they left the meeting. Dr Tizzard, HRA Director of Policy also left the meeting.

4. RESUBMITTED APPLICATIONS

a. 18/CAG/0091 (Previously 17/CAG/0178) – Connected Bradford Linked Education and Healthcare Research Database

Context

Purpose of Application

This application from the Bradford Teaching Hospitals NHS Foundation Trust set out the purpose of medical research which will establish a research database aiming to understand the relationship between child health issues and educational attainment levels within the Bradford and Airedale locality.

The sample to be included within the database will be all individuals within the Bradford and Airedale locality who were born between 01 January 1988 and 01 September 2014. It is proposed that routinely collected data from the following sources will be linked to create the research database:

1. Primary Care data from all 88 GP practices across the Bradford and Airedale region,
2. Secondary care inpatient, outpatient and emergency care data from Bradford Teaching Hospitals NHS Foundation Trust and Airedale NHS Foundation Trust,
3. Community Care data from Bradford District Care Trust,
4. School Education data from Bradford Council and North Yorkshire County Council who receive this information direct from the schools and,
5. Assessment data from the National Pupil Database at the Department for Education.

Data sources four and five detailed above are out of remit for the CAG, as they do not fall within the definition of confidential patient information as defined in s251(11) of the NHS Act 2006.

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

Confidential Patient Information Requested

Cohort

Patients within the Bradford and Airedale region, born between 01 January 1988 and 01 September 2014. The sample size is estimated to be 220,000 patients.

Confidential patient information will be provided by all healthcare providers participating in the study, in order to facilitate linkage across datasets. The following items of confidential patient information are requested the purposes described:

- Name – linkage
- NHS number - linkage,
- Date of birth – linkage,
- Address (First Line) – linkage,
- Postcode – linkage and analysis,
- Sex – linkage and analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

The CAG acknowledged that this application was a resubmission of the previously considered 17/CAG/0178, which was reviewed at the meeting held on 09 November 2017. The applicants had provided a revised application form which was supported by a detailed covering letter addressing the request for further information which had been identified as part of the previous review.

Public Interest

The CAG was assured that the application defined a clear medical purpose, which was medical research. Under the previous review, Members were unsure of the public interest in the project and had asked the applicants to consider whether the proposal would be more appropriately classified as a research database. The revised application provided as part of the resubmission had been reclassified as a research database. The applicants had also provided a clearer overview of the proposed research areas which the database would be used to support together with additional information evidencing the wider public interest in the activity progressing.

The Group recognised that the potential benefits which were anticipated from the project were quite generic; however, Members were in agreement that the proposed research topics which were cited in the application were important areas which could be addressed by the database and there was a public interest in this proceeding. The CAG acknowledged that considerable efforts had been made by the applicants to improve the project design and clearly articulate the overarching potential public benefit in the activity progressing and was satisfied that assurance had been provided against the concerns previously raised in this area.

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 clarified within the revised application that the cohort to be included within the project was estimated at 220,000 patients. The Group was assured that consent was not feasible for a cohort of this size and raised no further issues in this area.

- Use of anonymised/pseudonymised data

The CAG remained assured that processing of confidential patient information was required in order to facilitate the linkage between the various clinical and educational datasets.

Justification of Identifiers

The applicants had revised the items of confidential patient information required to facilitate linkage in the project and were seeking support to include the first line of the address and postcode only, rather than full address. It was explained that this level of detail was required to ensure integrity of data-matching due to the high population of residents with South Asian ancestry within the target geographical area, which were known to have similar names. Members were assured by the rationale provided and raised no further issues around the items of confidential patient information requested.

Scope of Support

The remit of the CAG set out in the Health Service (Control of Patient Information) Regulations 2002 applies to confidential patient information (as defined within the NHS Act 2006). The recommendation of support provided extended to the release of confidential patient information from GP practices within the Bradford and Airedale region (primary care data), Bradford Teaching Hospitals NHS Foundation Trust and Airedale NHS Foundation Trust (secondary care inpatient, outpatient and emergency care data) and Bradford District Care Trust (community care data). Support was also extended to the release of confidential patient information from Bradford Teaching Hospitals NHS Foundation Trust to Bradford Council, North Yorkshire County Council and the Department for Education for linkage with education data; however, it was noted that it was the responsibility of these data controllers to ensure that a legal basis had been established to support the disclosure of educational data from these sources.

Scope of Clinical Data Requested

Members considered the breadth of clinical data which had been requested as part of the project. The Group agreed that in reclassifying the activity as a research database, a stronger justification had been provided to support the extensive dataset which would be linked within the project. The inclusion of abuse data was discussed further and it was commented that there may be a more consistent way of collating this information from educational records, as detail would be held as part of safeguarding review. It was commented that the information within health records may be inconsistent due to the use of different read codes. Members agreed that further clarification was required around how this data would be recorded and which organisation would be supplying the information.

Data Flows

The Group agreed that the data flows within the project were clear in the revised application and was assured that access to confidential patient information was limited to individuals with appropriate authority. It was also confirmed that researchers would only be able to access an anonymised dataset.

The main application stated that the data linkage was a one-off process; however, the supporting information sheet suggested that records would be linked over time. This point would be queried with the applicants to ensure the data linkages proposed within the project were clearly understood and appropriately described.

Database Access

The CAG considered the database access arrangements which had been described within the application. It was acknowledged that the Connected Bradford Research Database Committee would review applications to access the database; however, it was unclear what the application process was and how the Committee would assess these proposals. Members agreed that further information was required in this area to understand the application process, particularly in relation to organisations which are not part of the

Connected Bradford partnership. It was commented that sight of any policies to support the application assessment and approval process would be helpful.

Exit Strategy

The applicants confirmed that upon completion of data linkage, all confidential patient information will be deleted, leaving a pseudonymised dataset to be used for research analysis. The applicants had anticipated this process would be completed by 31 December 2019.

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 considered the revised participant information materials which were provided and recognised that these had been developed in consultation with patient and public focus groups. Members were mindful of this interaction; however, it was commented that the references to the processing of confidential patient information in order to create the research database were no longer clear in the documents. It was also noted that the text moved between formal and informal presentation with a mix of technical and lay language. The CAG recommended that further work was undertaken to address these points to ensure that the information provided in the public domain clearly explained what the project involved.

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 patient and public involvement programme within the Bradford area was familiar to the Group which recognised that this population was integrated well with healthcare. It was recognised that the applicants had established an impressive programme of activity in relation to the project and no issues were raised in this area.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed scores for Bradford Teaching Hospitals NHS Foundation Trust, Bradford District Care Trust, Airedale NHS Trust, City of Bradford Metropolitan District Council, North Yorkshire County Council and Apollo Medical Software Solutions Ltd. had been published in respect of version 14.1 (2017/18) of the toolkit; however, these self-assessments had not yet been reviewed by NHS Digital. It was also noted that assurance would need to be provided for the Department for Education. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. This would need to be addressed by the applicant.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. It was recognised that an amendment was being progressed via the REC to change the classification of the project to a research database. Confirmation that the amendment has received a favourable ethical opinion was required prior to any recommendation of support coming into effect.

Confidentiality Advisory Group Advice Conclusion

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

Request for Further Information

1. Provide further information around the abuse data which will be included within the database – confirm which organisation would be supplying this, how this would be recorded and what data would be provided.
2. Confirm whether the linkage would be undertaken on a one-off basis or over time and revise any documentation accordingly.
3. Provide further information around the assessment and approval process which would be undertaken by the Connected Bradford Research Database Committee when assessing applications to access the database. Provide copies of any policies/protocols which will support this.

Recommendation

1. The CAG acknowledged that the patient information materials have been developed in collaboration with patient focus groups and does not require that these are changed. It is recommended that these documents are revised to ensure that the use of confidential patient information in the creation of the pseudonymised research database is correctly explained and to ensure that the documentation is presented in a way using language which would be accessible to wide audience.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending – Confirmation required that substantial amendment has received a favourable opinion**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Pending – confirmation of assurance against V14.1, 2017/18 of the IG Toolkit is required for the following organisations:**

- Bradford Teaching Hospitals NHS Foundation Trust (Org Code: RAE),
- Bradford District Care Trust (Org Code: TAD),
- Airedale NHS Trust (Org Code: RCF),
- City of Bradford Metropolitan District Council (Org Code: 209),
- Apollo Medical Software Solutions Ltd. (Org Code: 8HH66),
- Department for Education.

5. NEW APPLICATIONS – Research

a. 18/CAG/0090 - What changes for patients in Medium Secure Care?

Context

Purpose of Application

This application from Abertawe Bro Morgannwg Health Board set out the purpose of medical research which aims to identify how Medium Secure Services in Wales have changed over the last twenty years in relation to thresholds for clinical decision making, care pathways, patient experiences, and outcomes. The aim is to help inform future practice and improve patient experiences and outcomes.

Archived healthcare records of individuals admitted to and discharged from medium security in Wales in the last twenty years will be examined in terms of collecting data linked to care pathways, clinical decision making, and clinical profiles of patients. From this data, individuals discharged to less secure or community placements, who have available follow up records, will be followed up to collect forensic, clinical and social outcome data. The research also include a second element in which a subset of discharged individuals still in contact with mental health services, and their carers will be invited to participate in a semi-structured interview regarding their experiences and perspectives of secure mental health care, and their quality of life subsequent to medium secure care. This activity will be consented and is out of scope for CAG consideration.

A recommendation for class 1, 3, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

- All adult patients were admitted and discharged from a Welsh Medium Secure Unit over the last 20 years.
- It is estimated that there would be 300 patients included within the study.
- Deceased patients would be included if their death had occurred within the last 10 years.

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

- Name – linkage and sample verification,
- NHS number – linkage,
- Date of birth – linkage,
- Date of death – sample validation,
- Local Health Board identifier – linkage,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose through medical research, which aimed to improve patient experience in medium secure units by studying how the services have changed within Wales over the previous 20 years, to help inform future practice. Members recognised that research was lacking in this area and accepted that there was a public interest in this activity proceeding.

Scope of Support

The remit under which the CAG can advise is defined in section 251 of the NHS Act 2006 and its Regulations, which enables the common law duty of confidentiality to be temporarily lifted so that confidential patient information can be accessed or processed for specific purposes outside of the direct care team, without seeking consent from the individual patient, and without the data controller being in breach of this common law duty. Members considered the various elements of the study and discussed which involved a breach of the common law duty of confidentiality.

The Group was in agreement with the applicant that support was required to for the disclosure of confidential patient information from the medium secure unit to the local collaborators at the wider Health Boards, to allow the Student Investigator access to confidential patient information at the wider Health Boards and the disclosure of confidential patient information to the local collaborators at the Ministry of Justice.

It was advised in response to queries that support under the Regulations was not required to support the student investigator's access to confidential patient information at the medium secure unit as the individual was under an honorary employment contract. The Group commented that being appointed by honorary contract did not provide a legitimate basis for that individual to access confidential patient information. The CAG takes the perspective that a member of the care team is someone that a patient or service user would reasonably recognise to be as such, as part of delivering specific interventions as part of providing 'direct care'. Members agreed that the applicant would be required to confirm the legal basis in relation to the common law duty of confidentiality to legitimise the student investigator's access to patient medical records. Alternatively, the applicant should confirm in response that support under the Regulations was required to extend to this activity.

The remit of the CAG set out in the Health Service (Control of Patient Information) Regulations 2002 applies to confidential patient information (as defined within the NHS Act 2006). The recommendation of support extended to the release of confidential patient information from the medium secure unit to the Ministry of Justice for linkage with wider forensic data; however, it was noted that it was the responsibility of the data controller of this dataset to ensure that a legal basis had been established to support the disclosure of this forensic data to the Health Board.

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, due to the retrospective nature of the patient cohort and the potential for consent to introduce a bias to the research findings, consent was not feasible for this project.

- Use of anonymised/pseudonymised data

The Group acknowledged that confidential patient information was required to facilitate linkage with the wider data sources, which could not otherwise be achieved.

Cohort

It was noted from the project filter page within the IRAS application that the applicant did not intend to include any prisoners within the study cohort; however, Members commented that the fact that some patients previously treated within the medium secure unit could potentially now be prisoners was not explored in the application. Clarification was required from the applicants whether it was the intention to exclude individuals who fell into this category from the application. It was noted that, if the intention was to include these individuals, revisions to the application may be required in order for the project to be reviewed by an appropriate Research Ethics Committee which was specifically flagged to consider prison research.

Members were unclear whether the local collaborators within the wider Health Boards would be aware that patients had previously been treated within a medium secure unit. A concern was raised in relation to this point as, if this was not known within the follow-up Health Boards, the project would lead to a sensitive disclosure about the patients included within the project sample. Confirmation would be sought from the applicants around this point. If it was confirmed that the patient history was not known at the local collaborator level, the applicants would need to provide assurance that this information would not be disclosed by the study team.

Justification of Identifiers

Members commented that NHS Number and hospital number had been referenced interchangeably between the application form and wider study documentation and it was unclear whether both identifiers were required. It was understood that hospital number was generally a local ID and may not be recognised in the datasets of wider organisations. It was agreed that clarification would be sought around which items of confidential patient information were required for the project.

It was acknowledged that date of death would be required for sample validation to ensure that any deceased patients who were included in the cohort met the project inclusion criteria. The Group was unclear when this item of confidential patient information would be deleted from the study dataset and 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 recognised that the applicants had been engaging with Hafal, a voluntary organisation which supports individuals with mental health difficulties. It was also referenced that the applicant had engaged with the Service User and Carer Participation Service (SUCPO); however, it was unclear whether this service formed part of Hafal, or was a separate entity. It was agreed that further information would be required from the applicant to understand the scope of the activity which had been undertaken in this area.

The Group recognised that the activity in this area engaged with individuals with mental health difficulties, but it was unclear whether this covered interaction with individuals who had encountered medium secure services because of criminal activity. Members agreed that this was a key element of the overall project focus and it was important that views of patients within this area were sought around the project. It was acknowledged that there were various charities which may be able to assist in arranging activity with an appropriate and patient and public group. It was agreed that the applicants would be required to provide a plan of additional activity in this area for consideration by the CAG, which would need to be taken forward as the study progressed. Feedback from the activity would be required as the study progressed.

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 commented that the communications strategy was required to focus on the data linkage elements of the overall study which required support under the Regulations to legitimise the data processing. It was noted the some of the information provided focussed on the qualitative interview element of the study, which would be consented. As such, the general information sheet which had been provided for all sites would require revision to ensure that an objection mechanism is described to enable patients to dissent to this use of their data within the project. An overview of how the dissenting mechanism would be operated would also be required. It was also commented that the document would benefit from further revision to make the content accessible to a wider audience. It was recommended that guidance is sought from a patient or service user group around the document content.

Whilst it was noted from the response to the queries that there was no formal mechanism by which to check for evidence of historical dissent for use of data for purposes additional to direct care, confirmation was required whether patient records would be checked more widely for evidence of historic consent.

Members further commented that information around the project should be displayed on the websites of the applying Health Board, together the wider Health Boards which are collaborating on the project. Confirmation of this point would be sought from the applicants.

It was commented that, as the project was being undertaken in Wales, the applicant was required to comply with the Welsh Language Act 1993. It was identified that the project had been considered by a Welsh Research Ethics Committee and as such, this was likely to be in hand; however, the application form did not confirm this. The CAG agreed to reference this point within the recommendation for information purposes only.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. It was acknowledged that the application had received a provisional opinion from Wales REC 7. It was noted that one of the outstanding points included within the request for further information within the provisional opinion was to provide a supported recommendation from the CAG. As evidence that a favourable ethical opinion is in place is required prior to any final recommendation of support from the CAG coming into effect, this point would be followed by the Confidentiality Advice Team with the named REC.

Security Assurance Arrangements

The CAG has been provided with a report titled System Level Security & Governance Assessment (SLSGA) Formal Response NWIS REF – 1518-01. The assessment score for Abertawe Bro Morgannwg University Health Board and Cardiff Metropolitan University is 89% and this score has been provided in relation to this specific CAG application. It was acknowledged that NHS Wales Informatics Service had attached actions which required resolution as part of the assessment – confirmation would be required at the time of annual review that these actions had been addressed and assurance was still in place via the SLSGA.

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. Confirmation should be provided of the legal basis under the common law duty of confidentiality support the Student Investigator's access to confidential patient information at the medium secure unit. Alternatively, support under the Regulations should be formally requested to extend to this activity as required.
2. Clarify whether any historic patients who are traced to be current prisoners would be included in the study cohort. If so, provide confirmation that the relevant approvals have been sought for research involving prisoners.
3. Confirm whether collaborating Health Boards would already be informed of the patient's historic treatment at the medium secure unit. If not, clarify what steps would be put in place to prevent this disclosure being made through involvement in the study.
4. Confirm whether NHS Number and Hospital ID are both required for the purposes of the study – if so, provide a clear justification for each data item.
5. Confirm when date of death will be deleted from the dataset.
6. Patient and Public Involvement and Engagement – further information is required in this area to address the following points:
    a. Provide further information around the Service User and Carer Participation Service (SUCPO) which has been involved with the project,
    b. Further work should be planned in order to engage with patients who were previously treated via medium secure services because of historic criminal activity – provide an overview of the planned work to be undertaken in this area.
7. Patient Notifications and Dissent – further information is required to address the following points:

a. The general patient information leaflet should be revised to make the document more accessible to a wider public audience. The document should also be updated to include information around how an individual can object to the use of their data in the study,
b. It is recommended that guidance is sought from patients and the public around the content of the document,
c. Provide an overview of how the objection mechanism will be operated and respected for the study,
d. Clarify whether patient records will be checked for evidence of historical dissent against use of data for purposes additional to direct care,
e. Confirm that information about the study will be displayed on the Abertawe Bro Morgannwg University Health Board website together with the websites of the collaborating Health Boards. Provide a copy of the text to be displayed,
f. Confirm that the project complies with the Welsh Language Act 1993.

Specific Conditions of Support (Provisional)

1. Further patient and public involvement and engagement activity would need to be progressed in line with the planned activity provided in response to the provisionally supported outcome.
2. Favourable opinion from a Research Ethics Committee (**Pending**).
3. Security assurance arrangements (**Confirmed – NWIS SLSGA received 01 June 2018).**

b. 18/CAG/0094 – Ambulance CPAP: Use, Treatment Effect and Economics feasibility study

Context

Purpose of Application

This application from the University of Sheffield set out the purpose of medical research which aims to assess whether it is possible and worthwhile to undertake a full-scale study comparing continuous positive airways pressure (CPAP) delivered by paramedics to standard oxygen treatment for acute respiratory failure, and if so, how this trial should be carried out. The trial will also determine whether there are sufficient patients presenting with acute respiratory failure to make a large scale trial investigating the effectiveness of CPAP feasible. Evidence will also be collected to demonstrate that it is possible to randomise patients, collect data and follow up patients with acute respiratory failure in any future definitive trial.

The trial will be carried out within the West Midlands Ambulance Service. Paramedics will identify adults with acute respiratory failure when attending 999 emergency calls. The aim is to include 120 participants in the study – half will be randomly assigned to a group that will receive CPAP, while the other half will be treated with standard oxygen therapy. All the patients will then undergo normal hospital treatment and be followed up for a month to see if they survive. Patients will be recruited to the trial under emergency research procedures, whereby verbal consent will be sought from those patients with capacity to provide this. Patients who are assessed as without capacity to consent will be included within the trial without a verbal approach for consent. After arrival in hospital, research paramedics will approach patients, in order to seek informed consent for their continued involvement in the study. If the patient does not regain capacity, advice will be sought from a personal or nominated consultee around the patient's ongoing participation in the trial.

The trial has already begun recruitment; however, it was found that some patients were not well enough to be approached for consent about the study and subsequently died before this approach could be made. The rationale for the submission to the CAG is that the applicants are seeking support to access confidential patient information for patients who were enrolled in the trial, but died in hospital prior to an approach being made around consent into the trial. The trial steering committee agreed that data in relation to this cohort of patients was important for the safety analysis of the study findings.

No confidential patient information will be recorded in relation to these patients; however, the research paramedics will require access patient's medical records in order to extract relevant clinical information 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

The cohort to be included in the trial is as follows:

- Adults aged over 18 years with acute respiratory distress, identified by paramedics responding to 999 calls.
- The sub-cohort of patients of relevance to the CAG application is those who were enrolled in the trial, but died in hospital, prior to being approached for informed consent for their participation.

The research paramedic will have access to the full hospital record of the patient in order to extract the data relevant for analysis. The following items of confidential patient information are requested for the purposes of the identified:

- Name – to identify enrolled patients in hospital records systems,
- Date of death – recorded in days since admission – analysis
- Sex – analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose through medical research. Members recognised that there was a strong public interest in this pilot study proceeding as evidence from trials from outside the UK showed that CPAP was a more effective treatment and it was important that this was investigated within the NHS environment.

The Group acknowledged that the trial had begun recruiting and was operating under the requirements for emergency research and subsequently following the requirements of the Mental Capacity Act 2005. The application to the CAG came about as a sub-cohort of patients had died in hospital before the patient could be approached directly for consent and before the recruitment provisions established to comply with the requirements of the Mental Capacity Act 2005 could be enacted. As the current trial is a feasibility study only, which aimed to inform a full trial in future, it was identified by the Trial Steering Committee that, in the interests of ensuring a safe and accurate analysis was undertaken of the feasibility study findings, information around this sub-cohort should be included in the analysis. Members acknowledged the importance of these results to the overall findings and were content that the public interest threshold had been achieved.

Practicable Alternatives

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

- Feasibility of consent

The Group recognised that the applicants were attempting to seek consent, or consultee declaration to support all patients' inclusion in the trial; however, support under the Regulations was required to enable the research paramedic's access to the records of patients enrolled in the study that died before consent could be sought.

- Use of anonymised/pseudonymised data

Access to confidential patient information in medical records was required in order to extract the pseudonymised data for analysis.

- Data Extraction by the Direct Care Team

The applicants had provided confirmation that the hospital Trust sites which were involved in the study did not have capacity to undertake the data collection on behalf of the project. Members were assured by the rationale provided and agreed that support under the Regulations was appropriate in this instance.

Scope of Support Required

It was noted within the supporting protocol that, should a patient be discharged from hospital prior to the approach for consent into the trial, the research team would contact the patients at home in order to seek consent. Members were unclear under what legal basis this approach for consent was made to patients or how the research team acquired the required contact details. It was agreed that clarification was required around this activity – if support under the Regulations was required to extend to this additional cohort, the applicants would be required to describe the data access and flows required to support this element.

Justification of Identifiers

The CAG was assured that the items of confidential patient information requested were proportionate and appropriate to the activity. Members were assured that access to medical records was required to enable extraction of the relevant data for 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. It was acknowledged that support under the Regulations was required to enable access to the patient records – it was confirmed that only pseudonymised data would be extracted for analysis.

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 the level of patient and public involvement within the study via the established group, which had confirmed support to the revised protocol enabling access to deceased patient records. No further issues were raised in this area.

Patient Notification and Dissent

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

The applicants had provided a detailed overview of the trial communications strategy, which included the display of posters within the Trust A&E departments and with the ambulance Trust. It was also confirmed that there was a trial Twitter feed and dissemination of information via patient and public information groups. Members agreed that this was appropriate activity; however, sight of the posters was required by the CAG before support could be recommended.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted NHS Digital's review of the self-assessed scores for all organisations involved in the study were required before any recommendation of support could be provided. Assurance is currently provided against version 14.1 (2017/18) of the toolkit. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. This would need to be addressed by the applicant.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Evidence of the favourable ethical opinion in relation to the amendment to include access to deceased patients' data was required prior to any recommendation of support coming into effect.

Confidentiality Advisory Group Advice Conclusion

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

Request for Further Information

1. Provide further information around the contact which is made with patients who are discharged from hospital prior to consent to participate in the trial being taken – under what legal basis is confidential patient information processed in order to facilitate this approach for consent. If support under the Regulations is required to extend to this activity, this would need to be appropriately described in the application.
2. Provide copies of the patient notification posters which would be displayed in the Trust A&E and Ambulance Trusts for consideration.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending – confirmation of favourable ethical opinion of the substantial amendment**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending – confirmation of NHS Digital review of Version 14.1, 2017/18 IG Toolkit submissions for the following organisations:**

    - University Hospital of North Midlands NHS Trust – RJE,
    - Burton Hospitals NHS Foundation Trust – RJF,
    - The Royal Wolverhampton NHS Trust - RL4,
    - Heart Of England NHS Foundation Trust - RR1,
    - East Cheshire NHS Trust – RJN,
    - University Hospital Birmingham NHS Foundation Trust – RRK,
    - Sandwell and West Birmingham Hospitals NHS Trust – RXK,
    - University Hospitals Coventry And Warwickshire NHS Trust – RKB,
    - George Eliot Hospitals NHS Trust – RLT.
    - Derby Teaching Hospitals NHS Foundation Trust – RTG (V14.1 confirmed satisfactory).

c. 18/CAG/0100 – ORION-4

Context

Purpose of Application

This application from the University of Oxford set out the purpose of medical research which is a Clinical trial of an Investigational Medicine Product (CTIMP Study) which is assessing a new cholesterol lowering treatment, which if shown to be effective, could have a major impact on the number of people dying of vascular disease or suffering strokes or heart attacks in the UK. The application has been submitted to the CAG under the Precedent Set criteria one – participant identification studies, to enable a large sample of potentially eligible patients to be identified and invited to participate in the study. The UK sample size is estimated at 12,000 patients, which will be randomised on a 50/50 basis to receive the experimental drug versus placebo. The CAG is only required to consider participant identification and recruitment element of the study – after which, patients will provide informed consent for their involvement in the study.

Acute Hospital Trusts and NHS Digital will undertake a search to identify potentially patients based on the inclusion criteria. This information will be shared with the Clinical Trial Service Unit at the University of Oxford to enable the establishment of a pre-screening database. List screening will be undertaken via NHS Digital prior to invitation letters being issued to potentially eligible patients.

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

Confidential Patient Information Requested

Cohort

- All patients aged 55 years and over, with a history or evidence of cardiovascular disease through at least one of the following: myocardial infarction, ischaemic stroke or peripheral arterial disease (evident by lower extremity artery revascularisation or aortic aneurysm repair.
- It is estimated that 400,000 patients will be invited across England, Wales and Scotland in order to recruit the required patient cohort of 12,000 patients.
- Alternative arrangements are being made via the Public Benefit and Privacy Panel for the recruitment of Scottish patients.

The following items of confidential patient information will be disclosed by Acute Hospital Trusts and NHS Digital in relation to potentially eligible patients to the Clinical Trial Service Unit at the University of Oxford, for the purposes as set out below:

- Full name and title – to facilitate invitation,
- Full latest address and postcode – to facilitate invitation,
- Date of birth – to ensure eligibility and sample validation,
- NHS number – to facilitate invitation and sample validation,
- Hospital number – to facilitate invitation and sample validation,
- GP Registration – to facilitate invitation,
- Sex – sample validation,
- ICD-10 or other diagnostic or procedure codes – to ensure eligibility
- Fact of death – sample validation

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that there was an appropriate medical purpose in the application activity, which was medical research. Members were assured that there was a public interest in the application activity

proceeding as the investigation of drugs to lower cholesterol could provide important treatments in the care of patients with vascular disease and the prevention of strokes and heart attacks.

Practicable Alternatives

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

- Feasibility of consent

The CAG was assured that it was not feasible for the direct care teams to undertake the recruitment process due to the number of patients who would be invited to participate in the trial. Support under the Regulations was sought to support the recruitment process only as patients would provide their consent for continued participation or withdraw.

- Use of anonymised/pseudonymised data

Confidential patient information is required to facilitate the invitation process which could not be otherwise achieved.

Justification of Identifiers

The Group was unclear why both NHS Number and Hospital number were requested as part of the dataset and it was agreed that confirmation would be sought from the applicants.

Data Flows

The CAG considered the data flows which had been described within the application and it was queried why both NHS Digital and Acute Trusts were providing confidential patient information in relation to potentially eligible patients to be invited to the trial. Members commented that, if the data was provided by NHS Digital only, this would reduce the requirement for list cleaning as Type 2 objections/national opt-outs would already have been applied to the data prior to release to the applicants. This would also reduce the flow of confidential patient information within the study. It was agreed that the applicants would be required to provide stronger rationale, based on evidence of from the previous trials which they had facilitated to support these proposed data flows.

The Group was also unclear the applicants intended to link with NHS Wales Informatics Service (NWIS) in order to access information within the Patient Episodes Database Wales (PEDW), in relation to Welsh patients. Clarification would be sought from the applicants around this element.

Members were also unclear how regularly invitations would be sent which was important to ensure that list cleaning which had been applied by NHS Digital was current. It was agreed that further information around the timeliness of the data flows would be required from the applicants.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicants had explained that all confidential patient information would be need to be retained for the seven year recruitment period, to ensure that patients who had previously been invited to participate in the study did not receive any further invitations if they had declined to participate. The CAG was content to support this rationale; however, it was commented that, should a patient wish their data to be deleted from the trial recruitment database, this should be respected but the risk of receiving further invitations would need to be explained to the patient. Confirmation was required from the applicant that any patient dissent would be respected and data deleted from the database.

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 recognised that a good programme of patient and public involvement and engagement activity had been established for the trial and would be ongoing throughout. No issues were raised in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right 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 drafted website text which had been provided to support the application. It was agreed that document required revision to make the text more accessible to a wider audience. It was also noted that detail in relation to the dissenting mechanisms which were available to patients could be made clearer. The Group further commented that it would be helpful to explain within the website information that previous dissent (type 2 objections/national opt-outs) would be applied to the sample prior to data being transferred to the University of Oxford for the invitation process. It was also agreed that the text should explain the co-sponsoring arrangements for the study, including reference to The Medicines Company. It was suggested that the patient and public panel established for the study should be approached to assist with the revision of the website text.

The CAG also noted that the option to dissent to participate in the trial should be made clearer in the patient information sheet, which formed part of the trial invitation. It was noted that the invitation letter which would accompany the information sheet had not been submitted and sight of this document would be required.

It was noted that, in response to queries, the applicants had stated that patient-facing documents may require further revision following review by the Public Benefit and Privacy Panel and NHS Digital; however, it was not intended to submit the revised documentation to the CAG for review provided the level of transparency around the use of patient data was maintained. The Group expressed concerns at this point and it was agreed that revised documentation should be submitted to the Confidentiality Advice Team, to enable revisions to be assessed and a determination made around whether the changes required the consideration of the CAG.

Security Assurance

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

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 for the study is required prior to any recommendation of support coming into effect.

Confidentiality Advisory Group Advice Conclusion

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

Request for Further Information (Summary)

1. Clarify whether both NHS Number and Hospital ID are required to facilitate the invitation process. If so, provide further justification to support the requirement for both data fields.
2. Further information is required to understand why NHS Digital and Acute Trusts would be providing confidential patient information in relation to potentially eligible patients to be invited to the trial – provide further justification to support this proposed methodology, based on evidence from the previous trials which have been facilitated via similar recruitment processes.
3. Clarify whether NHS Wales Informatics Service have been approached about the study in order to access information from the Patient Episodes Database Wales (PEDW) in relation to Welsh patients.
4. Provide further information around the timelines of the invitation process, clarifying how long following the data cleaning process by NHS Digital invitations will be sent.
5. The website text should be revised, with input from the trial's patient and public panel to address the following points:
    a. To make this text more accessible to a wider audience,
    b. Include clearer information around the patient's right to object,
    c. Confirm that historically registered dissent would be respected prior to the invitation process,
    d. Provide information around the co-sponsorship arrangements for the study.
6. A copy of the participant invitation letter is required for review.
7. The patient information sheet should be revised to include clearer information around the patient's right to dissent.
8. Provide confirmation that, should a patient request the removal of their data from the trial recruitment database, the potential for future invitations to the trial would be explained to the individual, but the objection respected and data destroyed if this is requested.
9. Revised patient-facing documentation should be submitted to enable an assessment to be undertaken around whether the revisions require further review by the CAG.

Specific Conditions of Support (Provisional)

1. Support extends to England and Wales only – alternative arrangements should be made via the Public Benefit and Privacy Panel for the recruitment process within Scotland.
2. Favourable opinion from a Research Ethics Committee (**Pending**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending – University of Oxford – Medical Sciences Division – Nuffield Department of Population Health – Clinical Trial Service Unit, Version 14.1, 2017/18 – NHS Digital review pending**).

d. 18/CAG/0102 – HES and NICOR data linkage for cardiac failure population analysis

Context

Purpose of Application

This application from Kings College London set out the purpose of medical research which aims to understand population-based, patient-level analysis of heart failure in England over a five-year period using a data set created by linking HES and NICOR (National Institute for Cardiovascular Research Outcomes) databases. Analyses will look into the re-occurrence of hospitalisation after the initial diagnosis of heart failure, the influence of population factors on risk of re-hospitalisation and the resultant cost implications.

NHS Digital will be undertaking linkage between the NICOR (National Institute for Cardiovascular Outcomes Research) and HES databases and will provide a pseudonymised dataset to the applicant for analysis. The NICOR audit programme operates via support under the Regulations (application reference: 17/CAG/0071 (previously ECC1-06(d)/2011).

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

- All patients aged over 18 years old with heart failure in England between 2011 and 2016.
- Estimated sample size: 81,393.

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

- HES-ID – linkage,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members were assured that there was an established public interest in the proposed activity, as it could potentially lead to a better understanding of the care pathways for patient's following a heart failure diagnosis.

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 the size of the sample to be included in the study and noted that a wider disclosure of confidential patient information would be required in order to facilitate consent and was content that this was not feasible in this instance.

- Use of anonymised/pseudonymised data

The Group was assured that processing of confidential patient information was required in order to facilitate the linkage in the study.

Justification of Identifiers

The Group stated that the application form, in its current format did not clearly articulate which items of confidential patient information were required to facilitate the required study linkage. The information provided appeared to relate only to the detail which would be disclosed from NHS Digital to the applicant. Members agreed that a revised application form would be required which provided a clear overview of the items of confidential patient information which would be disclosed by the NICOR team to NHS Digital to facilitate the linkage. This would need to be supported by evidence from NHS Digital, who were acting as data processor for the project, that they had provided agreement in principle to undertake the linkage on the referenced items of confidential patient information.

A query had been raised with the applicant around the requirement for date of death to be provided. The applicant confirmed that fact of and date of death was not required for the project and would not be requested from the data providers. Members queried this response and it was commented that fact of death and survival post-diagnosis would be key details when undertaking a population-based analysis of patients following diagnosis with heart failure. The applicants would be asked to reconsider the relevance of these data items to the analysis when revising the application form.

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 acknowledged that NHS Digital would be pseudonymising the dataset prior to release to the applicants, which established the exit strategy from support under the Regulations.

NICOR Audit Programme – Legal Basis of Activity

The applicant had incorrectly stated within the study documentation that the NICOR audit programme operated on a consented basis and patients who were included in the audit had also provided consent for their data to be used in future research studies. The CAG commented that the NICOR audit programme activity operated with support under the Regulations (reference: 17/CAG/0071). NICOR also held a second application under the Regulations which supported the use of data collected for the audit programme for research purposes (17/CAG/0078). As both the audit and research activity associated with the NICOR programme operated with support under the Regulations, patients had not provided consent for any use of their data. This detail was provided for the applicant's information and would need to be updated within the application form.

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 activity in this area had been limited to a posting on the 'People in Research' website. It was noted that the information which was included in the posting was incorrect; as it referenced that the NICOR audit programme and associated research activity was consented so any feedback provided from this source would be from an inaccurately informed position.

The Group agreed that further activity was required in this area in order to seek the views of patients and public following an accurate description of the project methodology. It would beneficial if the views of patients with cardiovascular disease could be sought. An overview of planned work in this area would be required prior to any recommendation of support coming into effect. Feedback from this work would be required at an interim reporting point, which would be agreed by the CAG following consideration of the planned activity in this area. If the responses given are negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998. The Group acknowledged that the applicants had not yet established a communications strategy for the project. In response to queries, the applicant had advised that information about the study would be included on either the 'clinicaltrials.gov' or the Research Registry website. It was commented that it would not be appropriate to register the study with clinicaltrials.gov, as the project was not a clinical trial. It was also noted that the Research Registry appeared to be a resource intended for the research community, rather than patients and the public, so it was unclear how beneficial this site would be.

Members agreed that information around the study would need to be displayed on the University website as a minimum, providing details of the purpose of the study and an overview of the confidential patient information which would be used within the project. It would be helpful to include a link to the NICOR website within the text also. The applicants were also required to explore whether a study-specific dissent could be operated with NICOR and provide details in relation to this. Sight of the website text would be required prior to any recommendation of support coming into effect.

Confidentiality Advisory Group Advice Conclusion

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

Request for Further Information (Summary)

1. Further information is required to understand what items of confidential patient information will be released by NICOR to NHS Digital to facilitate the linkage. Evidence should be provided of agreement in principle from NHS Digital to this data linkage.
2. Reconsider whether the fact of and date of death are required in order to achieve the study aims.
3. A revised application form should be provided which accurately reflects the study data flows which have been clarified above. Inaccurate references to the NICOR programme (audit and research) operating on a consented basis should be removed from the revised application form.
4. Provide details of a revised plan of patient and public involvement and engagement activity which will be undertaken as the study progresses for consideration. Any activity in this area should provide an accurate description of the trial methodology and the use of confidential patient information in the production of the database which will be used for analysis.
5. A copy of study-specific patient notification text, which will be displayed on the University website, should be provided for consideration. This should include a clear overview of the study, how confidential patient information would be used and link to the NICOR website.
6. Contact should be made with NICOR to explore the possibility of a study-specific dissenting mechanism. The outcome of this discussion should be shared, and any relevant documentation revised to include details of the objection mechanism, where appropriate.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 19 April 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital undertaking data processing**).

6. MINUTES OF THE MEETING HELD ON 05 APRIL 2018

The minutes of the meeting held on 05 April 2018 were reviewed and accepted as an accurate record of proceedings with no required amendments.

7. CAG CHAIR REPORT

The Chairman's report was received by Members with no wider queries.

8. EDUCATIONAL ITEMS 2018/19

Members were reminded to contact the Confidentiality Advice Team or a Member of the Chair Team to raise any proposed educational items to be taken forward over the financial year.

9. ANY OTHER BUSINESS

Public Health England Annual Review PIAG 03 (a)/2001

The Confidentiality Advice Team informed members that Public Health England, under reference PIAG 03 (a)/2001 (cancer registration), had a number of conditions of support to meet by 25 May 2018 following their annual review in January 2018. Members noted this was the annual review where the SofS for Health and Care had strengthened the CAG initial recommendation to include specific deadlines in light of the media interest at that time and lack of clarity regarding anonymised disclosures.

Members were advised that Public Health England had failed to respond to the conditions of support and had not provided evidence they had complied with the conditions. The rationale given was work to undertake GDPR compliance. Members noted that PHE had been given a 10 working day window in which to submit the overdue evidence to demonstrate compliance with the support. It was advised that unless PHE met their conditions of support then the matter would be escalated directly to the decision-maker in the Department of Health as it was that legal decision that was not being complied with. The Advice Team would update the CAG if the outstanding response was not received.

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