Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

OCTOBER 2018

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1. APPLICATIONS

Group Members:

Name	*Notes*
Dr Patrick Coyle	Vice-Chair
Mr Anthony Kane	Lay Member
Mrs Diana Robbins	Lay Member
Mr Marc Taylor	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Head or Heart Database**

CAG reference: **17/CAG/0051**

IRAS project ID: **212148**

REC reference: **17/LO/0556**

Context

Purpose of Application

This application from University College London defined a research application which aimed to demonstrate the research potential of unconsented linkage between "dormant" (historical) trial data and administrative records for understanding long-term intervention effects. Through doing this, the applicants aim to evaluate the long-term safety and effects of giving nutritional supplementation in infancy on cognitive development. Data linkage is requested with HES (facilitated by NHS Digital) and the National Public Database (facilitated by the Fisher Family Trust), with initial referral to the NHS Patient Demographics service to complete the historic trial datasets with NHS numbers and addresses during school years to allow linkage with HES/NPD.

The cohort will be established from a unique series of eleven infant feeding trials with over 4,000 participants recruited between 1982 and 2001. The studies, which measured cognitive function at various points of follow up, struggled with low-response rates in later years, with retention as low as 12% by the age of 15 years., using conventional follow-up methods, it remains unclear whether the expected cognitive benefits sustain into adolescence and adulthood. Importantly, follow-up studies have also suggested that such interventions carry risks. As an example, in preterm infants nutrient-enriched diets that promote early growth were found to be associated with worse plasma lipid profiles and higher blood pressure in adolescence. The applicants explained that only a long-term follow-up of trial participants

could address the unexamined balance between cognitive benefits and suggested potential metabolic harms.

The applicants advise that the historical trials did not seek consent for linkage with administrative data. Due to the limited quality and availability of administrative records, linkage to administrative data was not an option that was available to the investigators at the time of recruitment to those trials (between 1982 and 2001).

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

Confidential Patient Information Requested

The following items of confidential patient information were requested:

- Name – linkage,
- NHS Number – linkage (only small number available),
- Date of birth – linkage and analysis,
- Date of death – analysis only
- Unit level postcode – linkage and deprivation score calculation,
- Gender – analysis,
- Ethnicity – analysis,
- Historical address details – linkage only.

The historic trials have a combined cohort of over 4,000 patients which will form the sample for study in this project.

Amendment Request

An amendment was submitted for consideration alongside the response to the provisionally supported outcome, due to a required change to the data processor undertaking linkage with educational data. The amendment described the following two changes:

1. Inclusion of the Fisher Family Trust (FFT) as a processor for linkage with education data,
2. Change to the data flows proposed for the project, to remove the requirement for confidential patient information to flow between NHS Digital and the educational data processor (now proposed as FFT).

Confidentiality Advisory Group advice

A sub-committee of the CAG considered the applicant's response to the request for further information detailed within the provisionally supported outcome in correspondence. The applicant had also provided interim responses in relation to some of the conditions which were attached to the provisional recommendation of support which were considered by the Sub-Committee.

It was understood that the pseudonymisation linkage key would need to be retained following linkage, whilst data cleaning and analysis are undertaken. Consider the possibility of this linkage file being held by a third party and provide response. If this is not deemed feasible, provide strong rationale to support this.

The applicant clarified that the link file would be passed to the data safe haven for the ADRC-E in Southampton – supplementary information was provided together with the named contact at this facility. Access to the pseudonymisation linkage key would not be possible for UCL researchers without authorisation from the senior data scientist at Southampton. The key will be retained for 15 years in case

re-linkage is required for the current or a future purpose (subject to further CAG and ethics approval). Access to the Southampton safe haven is possible from UCL through a CCTV monitored safe room at UCL with strict protocols for statistical disclosure controls on any outputs. However, access would not be possible for the pseudonymisation linkage key file without authorisation from the senior data scientist. The Sub-Committee was assured by the response provided – it was agreed that confirmation was required at the time of first annual review that the pseudonymisation linkage file was being held in a separate location from the analysis dataset.

It was acknowledged that the study data would be retained for 15 years following the closure of the study – at first annual review; provide further details around the future intentions for the study data to justify its onward retention for this duration.

The applicant explained that the project would create a valuable resource for future research on the long-term risks and benefits of infant dietary supplementation. This resource will grow more valuable as participant's progress through the life-course and develop more manifestations of cardiovascular or metabolic disease or outcomes related to cognitive function as they age.

Each additional research purpose using this resource will need to be considered in a separate ethics and CAG application and in applications to the relevant data providers. Any future data linkage and access will be allowed only if these permissions are approved.

The supplementary information was received and no issues were raised by Members.

Patient and Public Involvement and Engagement –

a. **Undertake additional patient and public involvement and engagement as the project progresses,**
b. **Seek input around how the patient notifications and dissenting mechanism can be improved,**
c. **Provide a report on actual and planned activity at first annual review.**

The applicant explained that they would extend the sign-posting to the website notification of the study by requesting links through related organisations, for example the Human Nutrition Unit in Cambridge, previously the MRC Dunn Nutrition Unit which initiated these trials. Webinars were also planned as the study progressed to promote wider activity through these channels.

The applicant also confirmed that they would present the study to the Great Ormond Street young person's advisory group, which is a group trained in reviewing research, to get their input to the study. A report about these activities will be provided at the first annual review.

Members received the interim information and agreed that formal reporting was required at the time of first annual review, in line with the conditions of support.

<u>Amendment Submission</u>

The Group recognised the efforts which had been undertaken by the applicant's in the intervening period to progress the necessary assurances required for the application. It was noted that the Department for Education was no longer facilitating linkage with the National Pupil Database directly – this confirmation had brought about the proposed change to the data processor. The data linkage would now be undertaken by the Fisher Family Trust – Members recognised that it had taken some time for this newly assigned processor to undertake the Data Security and Protection Toolkit and get this reviewed by NHS Digital. Assurance was provided against this submission on 13 September 2018.

Wider changes to the proposed data flows were described within the amendment form which reduced the flow of confidential patient information for the purposes of the project. In the proposed amendment,

NHS Digital would no longer be required to disclose confidential patient information to the provider of education data.

Members were assured by the applicant's response to the provisional outcome and detail within the amendment application and were content to provide a recommendation of support.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. Provide confirmation at the time of first annual review that the pseudonymisation linkage file and analysis datasets are being held in separate locations.
2. Patient and Public Involvement and Engagement –
   a. Undertake additional patient and public involvement and engagement as the project progresses,
   b. Seek input around how the patient notifications and dissenting mechanism can be improved,
   c. Provide a report on actual and planned activity at first annual review.
3. Patent Notifications and Dissent –
   a. Improve and broaden the patient notification and dissent mechanisms as the project progresses,
   b. Provide a report, together with any notification materials developed, at first annual review on actual and planned activity at first annual.
4. Favourable opinion from a Research Ethics Committee. **(Confirmed – London City & East REC issued favourable opinion on 22 April 2017. Substantial amendment confirmed 23 March 2018).**
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - UCL School of Life and Medical Sciences-Data Safe Haven, Version 14.1, 2017-18 published satisfactory reviewed grade, The Fisher Family Trust, confirmed standards met on the DSPT – equivalent to satisfactory rating on IGTK – by email 13/09/2018).**

Group Members:

Name	*Notes*
Dr Tony Calland MBE	Chair
Mr. Myer Glickman	
Mr Andrew Melville	Lay Member
Mrs Diana Robbins	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Child Health Clinical Outcome Review Programme – Long-Term Ventilation**

CAG reference: **18/CAG/0127**

Context

Purpose of application

This Healthcare Quality Improvement Partnership commissioned application from the National Confidential Enquiry into Patient Outcome and Death set out the purpose clinical audit which aims to review the quality of the delivery of care of patients receiving, or who have received, long-term ventilation and who range in age from 0-25. The organisation of care and clinical practice will be reviewed to identify potentially remediable factors in the care provided for children and young people. The audit is carried out across the UK, Guernsey, Jersey and the Isle of Man; however, the CAG remit extends only to data generated in England and Wales.

For the purposes of the audit, long-term ventilation is as 'ventilation provided every day for three months (including both invasive and non-invasive) where the intention is/was to discharge the patient home on the same level of continuing respiratory support (not home oxygen).

The audit will follow the standard NCEPOD retrospective questionnaire and case note review methodology on a sample of patients from hospitals, who match the inclusion criteria. Confidential patient information relating to eligible patients will be reported to NCEPOD from participating hospitals to enable a questionnaire to be sent to the clinician(s) involved in the patient's care, which will be returned with relevant copied extracts of the case notes to NCEPOD to undergo peer review.

Participating hospitals will be asked to identify all patients who meet the inclusion criteria over the two year period from 01 April 2016 to 31 March 2018. From the information, NCEPOD will sample cases which will include those patients who were newly commenced on long-term ventilation in the two year period, and those patients on the follow-up pathway. A limited number of cases will be randomly sampled for inclusion in the clinical questionnaire and peer review process to ensure hospitals are not overburdened. Sampling will include the following groups:

- A group of patients newly initiated on invasive long-term ventilation (initiations between 1st April 2016 – 31st March 2018) – clinical questionnaire only
- A group of patients who are not admitted to hospital during the study period – clinical questionnaire only

- A group of patients who have an acute admission to hospital during the study period – clinical questionnaire and case note review

Four questionnaires will be used to collect data for this study via a link to an online questionnaire housed on a dedicated NCEPOD server separate to the case identification data – the questionnaires will be linked by a unique NCEPOD case number only:

- Tracheostomy insertion questionnaire: A questionnaire will be sent to the named consultant responsible for undertaking the procedure (new insertions between 1 April 2016 –and 31 March 2018).
- Admission to hospital: A questionnaire will be sent to the named consultant responsible for the patient at the time of admission to hospital (where applicable).
- Ongoing long-term ventilation care: A questionnaire will be sent to the named consultant responsible for initiating and/or providing ongoing long term ventilation (all patients).
- (Main) Community nursing team: A questionnaire will be sent to the team responsible for providing the ongoing care to the patient in the community (all patients where applicable).

The case note review will focus on those patients who had an acute admission during the study inclusion dates. Where patients were transferred, notes will be requested from both the initial and subsequent admitting hospitals. NCEPOD will request photocopied/scanned copies of the relevant parts of the patient's notes to allow the peer review to take place and to identify other healthcare providers within the patient care pathway to enable additional questionnaires to be sent.

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

Patients from 0 up to their 25th birthday who were receiving, or received, long-term ventilation over a two year period from the 1 April 2016 to 31 March 2018 will be included in the review. It is estimated that 3,000 patients would be identified of which 500 clinician questionnaires would be issued with an aim to receive 250 sets of corresponding notes.

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

- NHS Number – sample validation and linkage,
- Hospital Number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Sex – sample validation and linkage,
- NCEPOD ID – linkage,
- Name – present in case notes; however, not required for the application,
- Postcode – present in case notes; however, not required for the application.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed within the provisional outcome in correspondence.

1. **Provide further information around the data flows involved with receipt of data from General Practitioners.**

The applicant confirmed that GPs were not being approached for additional information – any information which was used in the programme would be extracted from case notes. An updated protocol was provided to reflect this.

The Sub-Committee received the response and no further issues were raised.

2. **Additional information and revised patient-facing documentation is required in relation to the communications strategy to support the proposed activity to address the following points:**
   a. **Copies of all final patient-facing documents should be provided for review,**
   b. **Documentation should be specific to this activity, providing a clear overview of the two elements of the audit (clinician questionnaire and case note review) and providing clear information in relation to the patient's right to object to the use of their data,**
   c. **Is it recommended that guidance is sought from patient and public involvement representatives to ensure that the content and language used within the documents is accessible to a wider public audience,**
   d. **Established links with patient organisations, i.e. National Children's Bureau and WellChild, should be approached to widen the communications strategy for the project,**
   e. **Confirmation should be provided that the patient information leaflet will be distributed within the community settings, as well as being made available in hospitals, to ensure wide distribution of information in relation to the audit.**

The applicant submitted a revised document for consideration by the CAG. It was confirmed that the National Children's Bureau, a parent on the study advisory group and WellChild had been involved in the review of patient-facing materials. It was confirmed that the output of this activity was that one document should serve both as a leaflet and a poster. The applicant confirmed that the established networks with patient organisations would be used throughout the programme and had a close working relationship with the NCEPOD team. A copy of the overarching communications strategy was provided for information purposes.

The Sub-Committee received the response and supporting supplementary documentation. It was recognised that the final document had been reviewed and supported by the referenced patient groups. Members raised some points around the wording in the documentation and it was agreed that these revisions would be fed back as for information purposes to the applicant.

The following supplementary point was raised as a recommendation only within the provisional outcome – the applicant addressed this in correspondence.

1. **It is recommended that the protocol for raising concerns be revised to ensure this accounts for any concerns identified by care provided outside of the hospital to be appropriately raised.**

The applicant acknowledged the point queried by CAG and noted that the process had been established by HQIP. The applicant confirmed that the process had been revised for the programme use and feedback had been provided to HQIP around this.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

6. Support extends to data generated in England and Wales only.
7. Provide feedback at the time of first annual review around the involvement and engagement activities which have been undertaken with patients and their families in relation to the audit. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
8. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – National Confidential Enquiry into Patient Outcome and Death shows a satisfactory reviewed grade on Version 14.1, 2017/18**).

As the above conditions have been accepted or met, this letter provides confirmation of final approval. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Recommendation:

The following points were raised by Members in relation to the patient-facing information document as guidance only and compliance is not mandatory in order to comply with conditions of support.

1. The paragraph in relation destruction of programme records may be interpreted as hospital records would be destroyed by November 2019 – consider revision of the text here.

The opt-out information is unclear as it suggests that patients can only partially opt-out from the programme ('…opt out of identifiable information being used in this study'). This could be revised to 'you can opt-out of involvement in the study', to make the objection mechanism clearer.

Group Members:

Name	*Notes*
Dr. Liliane Field	
Mrs Diana Robbins	Lay Member
Dr Murat Soncul	Alternate Vice-Chair
Mr Marc Taylor	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **National Adult Community Acquired Pneumonia Audit 2018-19**
CAG reference: **18/CAG/0147**

Context

Purpose of application

This application from the British Thoracic Society set out purpose of a national audit programme into community acquired pneumonia in adults. The first British Thoracic Society (BTS) CAP audit took place in 2009/10, with re-audits in 2010/11, 2011/12, 2012/13 and 2014/15. The standards for the audits were derived from the 2009 update to the BTS Guidelines for the management of community acquired pneumonia in adults (the 'BTS Guidelines'). Over the years, a total of over 120 acute trusts have participated in the audit, involving over 24,000 cases of pneumonia.

To date, the CAP audit has not collected confidential patient information so has not required support under the Regulations. Data from the audits have shown a decreasing trend in mortality from CAP associated with improved processes of care. There is however evidence from GP databases and from HES data that variation in care of adults hospitalised with pneumonia exists across the UK. Previous BTS CAP audits have not assessed variation between sites. In contrast, recent national UK audits in both lung cancer and COPD have compared performance between sites to assess for variation in care and outcomes.

The aim with the BTS CAP audit 2018/19 is to assess variation in the care of patients hospitalised with pneumonia in the UK and seek explanations for any variation observed. In order to increase the value and data quality of the audit, it is proposed to link the BTS CAP audit data to routinely collected HES and ONS data. The BTS CAP audit dataset is rich in process of care measures whilst the HES dataset is strong in relation to patient baseline parameters and hospital outcome measures, but fails to capture CAP process of care measures. Linkage of these data sources will enable:

1. Analysis of variation of care according to a wider range of important outcome measures, including mortality, ICU admissions, hospital re-admissions and healthcare costs.
2. Improved case-mix adjustment of the audit cohort according to underlying co-morbidities and socio-economic parameters.
3. Health economic analyses.

The core aim of the project is to drive improvements in care, particularly in relation to the quality improvement objectives identified in 2014/15, by allowing participants to monitor their progress against these targets. In this round of audit (2018/2019) additional information will be provided on where variation exists in relation to these targets and performance generally, to allow sites to identify where quality improvement initiatives are needed locally.

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

The study population is hospitalised adults (16 years or older) admitted with a clinical radiographic diagnosis of Community Acquired Pneumonia (CAP) from 1 December 2018 to 31 January 2019. 150 Trusts are expected to participate in the audit and will be asked to enter as many cases as possible, with a minimum requirement of 60 cases per Trust. Limited information will be collected on patients who are deemed ineligible for inclusion in the audit; however, these patients are out of scope as confidential patient information will not be requested.

The following items of confidential patient information will be entered into the audit platform to facilitate linkage with HES and ONS datasets by NHS Digital:

- NHS Number,
- Home Postcode,
- Sex,
- Date of birth,
- Date of death.

Confidentiality Advisory Group advice

A Sub-Committee of the main CAG considered the applicant's below written response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. Confirm that the patient diagnosis review would be undertaken by a member of the direct care team.

The applicant confirmed that the audit would be undertaken on a retrospective basis, with case lists generated using ICD10 codes and screened against the further inclusion/exclusion criteria. It was confirmed that participating Trusts would be informed that the audit should be led by a Consultant Physician and the screening process/diagnosis review undertaken by a member of the direct care team.

The Sub-Committee was assured by the applicant's response and raised no issues in this area.

2. Confirm what lawful basis is being relied upon for the processing of data and special category data in order to show compliance against principle A of the GDPR.

The applicant confirmed that the British Thoracic Society relied on GDPR Article 6(1)(f) to support its data processing – legitimate interests.

The Sub-Committee received the response and no queries were raised.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. Patient and Public Involvement and Engagement strategy should be extended to enable additional activity to be undertaken as the audit progressed. An overview of the actual activity which has been carried out, together with details of the feedback provided, should be provided at the time of first annual review. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - British Thoracic Society and Westcliff Solutions Ltd have a satisfactory reviewed grade on V14.1, 2017/18**).

Group Members:

Name	*Notes*
Dr Tony Calland MBE	Chair
Mr. Myer Glickman	
Mrs Diana Robbins	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Connected Health Cities: Data linkage of urgent care data**
CAG reference: **18/CAG/0126 (previously 17/CAG/0024)**
IRAS project ID: **215818**
REC reference: **18/YH/0234**

Context

Purpose of Application

This application from University of Sheffield was provided as part of an amendment submission to the previously supported 17/CAG/0024. The initial project was conditionally supported on 19 April 2017 on the basis of a specific-project only, which collected routine NHS data from a number of providers of emergency and urgent care (EUC) in the Yorkshire and Humber region and linked the data to provide a coherent picture of EUC demand for an initial period of 60 months (2011 - 2015). A subsequent amendment was supported on 07 August 2017 which extended the data collection duration to include records up to the end of 2017. The scope of support was also extended at this time to include data from mental health records held by Sheffield Health and Social Care NHS Foundation Trust.

Amendment – Change to Project Classification

The revised application submission requested a change to the project classification, from a specific-project only to a research database. The database would comprise of the information which had been collated with support under the Regulations for the specific project under reference 17/CAG/0024.

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

Confidential Patient Information Requested

Identifiers required for validation/linkage:

- Name,
- NHS Number,
- Data of birth,
- Date of death,
- Address,
- Postcode (unit level) for deprivation scoring.

Identifiers to be retained for analysis:

- Gender,

- Ethnicity.

The specific identifiers are listed above. In particular, data on individual patient episodes will be collected from participating services. Participants will be anyone who uses the Yorkshire Ambulance Service (YAS)/ NHS111, access out of hours (OOH) services and/ or emergency departments (EDs) during the 60-month period of the study, between 2011 and 2015.

Routine data obtained from YAS/ NHS111, OOH services and acute trusts (with 24-hour consultant led EDs) within Yorkshire and Humber, who are served by YAS, will be collected. A 60-month period of data collection will take place, to include the most recent service data available. Data will be collected from routine electronic data sources i.e Ambulance Service Computer Aided Dispatch (CAD) Data and OOH/ED/inpatient Patient Administration Systems.

1. From YAS (999 and NHS 111 call data) items will cover:
   - caller name, address/postcode, date of birth, age, gender and NHS number)
   - All data associated with the patient episode of care, for example clinical /call characteristics (incident number, type of call, type of response), presenting complaint, incident details (location of incident, date/all times relating to the incident, mode of access, disposal/discharge, disposal status (alive/dead).

2. From the OOH/ED/inpatient Patient Administration system items will cover:
   - Patient identifiable details (patient name, address/postcode, date of birth, gender and NHS Number)
   - All data associated with the patient episode of care, for example date/times relating to the incident, incident number, mode of access, presenting complaint, investigations, treatments, disposal/discharge, diagnoses and disposal status (alive /dead).

A proportion of YAS (999 and NHS 111) calls and OOH attendances during the study period will be transported/ referred to participating EDs. A process of data linkage of those pre-hospital emergency and acute care episodes conveyed to the ED will take place, in order to understand and detail the full pathway of care undergone by these patients. In these instances, YAS CAD data and OOH data will be linked with the ED data of participating EDs.

Confidentiality Advisory Group advice

A Sub-Committee of the main CAG considered the applicant's below response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. Provide assurance that projects approved to use extracts from the research database will be line with the supported aims of the original project, with a focus on improving patient care and have an established public interest.

It was confirmed that projects approved to use data extracts from the research database must be aligned with the aims of the original project, with a focus on improving patient care and outcomes in urgent and emergency care and have an established public interest. It was confirmed that this had previously been stated as a point on the document for reviewers to consider when assessing applications. Wording was also added to the web text to clarify this to any potential applicants. Revised documentation was provided for consideration.

The Sub-Committee received the response and no further issues were raised.

2. Further information is required around the de-identification protocol for the research database, with particular reference to how the potential re-identification risk for patients has been assessed against the combination of data retained in the database.

The applicant advised that although direct identifiers will be removed, the richness of the research database created the risk of re-identification of patients. It was confirmed that each data extract request would be assessed individually based on the aims of the underlying project and the exact data fields requested. This assessment would include reviewing the number of fields requested (ensure the minimum number of fields are provided to answer the research question), frequency of coded events (for example, use of a minimum frequency rule) and re-formatting of fields (continuous to categorical, i.e. age to age group) where necessary. It is anticipated that these actions will minimise the risk of individual patients being re-identified during analysis of datasets.

The Sub-Committee received the response and was assured that an appropriate mechanism was in place to ensure any released data had been assessed to prevent patient re-identification.

3. Clarify whether it is intended that sector-level postcode would be retained. If so, a strong rationale would be required to support this retention as it was recognised that an existing condition support for the initial application was to fully delete postcode once deprivation scoring had been undertaken.

It was confirmed that this was error and the De-identification Protocol had been updated to reflect that postcode would be deleted from the research database. A revised document was provided for consideration.

The Sub-Committee received the clarification and revised document and raised no further issues in this area.

4. Provide a clear overview of the number of individuals who will have access to the database and their roles.

The applicant confirmed that processing of confidential patient information would be on as limited a basis as possible in order to achieve the stated purpose of linking the different provider data. It was confirmed that this would involve six named members of the research team.

The Sub-Committee received the response and no further issues were raised.

5. Confirm when the use of the confidential patient information held in the database for linkage will be completed, and therefore when the de-identification process for the research database will be completed.

It was confirmed that the study team aimed to complete the data linkage, verify the links and de-identify the research database by March 2019. This deadline was moved due to unforeseen delays in the data cleaning and the recruitment of Data Management staff. The applicant had included additional wording within the web text to clarify this to any potential applicants.

The Sub-Committee received the response and no issues were raised. The applicant was reminded that, when all confidential patient information had been destroyed and there was no longer a requirement for support under the Regulations, the Confidentiality Advice Team should be informed to ensure the project could be expired.

6. It is recommended that the lay/public representation on the Sheffield Connected Health Cities Data Sub-Group Committee is increased - confirm agreement to this point and provide an overview of how and when this would be achieved.

The study team confirmed that the lay/public representation on this group would be increased to ensure patients and the public are clearly represented within the oversight of the database. Advertisements for

these roles would be disseminated through existing links in the first instance for example, the Sheffield Emergency Care Forum (SECF), Yorkshire and the Humber Research Design Service PPI Searchable database, Academic Health Science Network, as well as using social media (Twitter, Facebook, etc), local community boards and newspapers. The applicant confirmed that the aim was to have full membership of the CHC Data Sub-group Committee in place by the end of December 2018.

The Sub-Committee received the response and raised no further issues in this area.

7. **Submit a revised poster to address the following points:**
   a. **Provide a clear overview of the history of the project,**
   b. **Explain that the research database can be accessed by the wider research community following an application process,**
   c. **Details should be provided around the timescale available to patients to raise an objection to the use of their data within the database, due to the pending de-identification process.**

A revised poster was provided which had been updated as requested.

The Sub-Committee considered the revised document. It was noted that whilst this was appropriate, Members commented that the language was complex in places and the document was quite dense. It was suggested the document may be further improved with further consideration by patient and public representatives. The CAG was content to provide a recommendation of support for the study on the basis of the current poster; however, it was agreed that a recommendation to seek views of the lay representatives.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. All pre-existing conditions of support related to 17/CAG/0024 remain applicable.
2. The pre-existing annual review cycle remains applicable, with the next annual review to be received four weeks before 19/04/2019, and then on an annual basis to this schedule.
3. Favourable opinion from a Research Ethics Committee (**Confirmed – 26 June 2018**).
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – University of Sheffield – School of Health and Related Research, V14.1, 2017/18 – reviewed satisfactory grade**).

Advisory Point:

The following is raised as advisory point only – formal response to the CAG was not required in relation to this point, which did not impact the recommendation of support.

1. It is advised that the study poster is reviewed by the project's patient and public representatives to seek views and possible revisions around the text and its accessibility.

Study title: Helicobacter pylori Screening Study: a randomised stomach cancer prevention trial

CAG reference: 18/CAG/0189 (replacement of CR6/2013)

NHS Digital ref: MR515

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	Head of Confidentiality Advice Service

Context

Purpose of application

This application from Queen Mary, University of London set out the purpose of a randomised controlled trial to determine whether screening and treatment of the infection in middle age can reverse the increased risk of stomach cancer in patients infected with *Helicobacter pylori*.

A recommendation for class support was requested to cover access to cancer data from the NHS Central Register at the Health and Social Care Information Centre. A cohort of 62,454 patients was flagged.

This application received provisional support in 2015, however the specific conditions of support remained outstanding at that time therefore support to avoid a breach of the common law duty of confidentiality was not in effect.

Confidentiality Advice Team advice

Practicable alternatives

The application detailed the need to retain confidential patient information as the questionnaires originally completed were on microfiche and identifiable data could not be removed from these records. Therefore, it would be necessary to retain identifiable data in order to link to questionnaires. The dataset used for analysis would be anonymised.

It was noted that at recruitment, the cohort were informed that named data may be used by BUPA or associated clinical researchers for the purposes of specific research projects. Questionnaires were completed by all participants at the beginning of the trial.

Patient notification approach

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

The Group had noted that limited information had been provided in relation to informing the relevant cohort and providing an opportunity to manage any patient objection. It was advised that efforts should be made to inform the cohort through websites, publications and user groups. At time of next annual review, the review would be expected to provide substantive information on what communications had taken place, would demonstrate that reasonable steps had been taken to inform the population, and any patient objection respected.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending final support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Provided.**
2. Continued efforts are to be made to inform the cohort about the continued processing of confidential patient information without consent, and for any objections to be respected. A clear report focusing specifically on the communications taken, content, and status of any patient objections, to be provided at time of next annual review, which is due no later than 12 months from date of this letter and on an annual basis to avoid jeopardising the future status of this activity.

3. Confirmation of suitable security arrangements via satisfactory IG Toolkit (or replacement) submission **Confirmed.** The applicant must note that satisfactorily reviewed (by NHS Digital) security assurances, for the duration of support and at each annual review stage must be evidenced at time of submissions.

2. NEW AMENDMENTS

Group Members:

Name	*Notes*
Dr Patrick Coyle	Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Effectiveness and Cost-effectiveness of 'Usual Care' versus 'Specialist Integrated Care': A Comparative Study of Hospital Discharge Arrangements for Homeless People in England**
CAG reference: **16/CAG/0021**
IRAS project ID: **166237**
REC reference: **16/EE/0018**

Context

Purpose of Application

This application from University College London set out the purpose of establishing the ways in which Specialist Integrated Homeless Health and Care (SIHHC) services are being developed and used to facilitate hospital discharge in England. The study also aims to examine the impact this is having on quality of care for homeless people admitted to hospital and whether this care can help prevent readmission to hospital shortly afterwards.

The first work package (WP1 –for which support is not requested) seeks to gain an informed understanding of the ways in which SIHHC services are being developed and implemented to facilitate

hospital discharge in England and the impact this is having on quality of care and organisational outcomes such as the prevention of readmission to hospital. For this work package, local service providers will be asked to identify and nominate potential participants.

The second work package (WP2, for which support is requested for datasets 1, 3, 4, and 5) is a data linkage and health economic analysis work package that will work with twenty sites across England where homeless patients have been admitted to hospital. A cohort of homeless people who have used specialist discharge scheme will be compared to a cohort of homeless people who have not used such provision. The study will also compare patient's hospitalisation history before and after engagement with specialist services. Analysis will also be undertaken to understand whether the outcomes are a factor of homelessness specifically or are tied to deprivation.

A recommendation for class 1, 2, 4, 5, and 6 support was requested to cover the activity specified in the application for work package 2, datasets 1, 3, 4, and 5.

Confidential Patient Information Requested

Access was requested to:

- Dataset 1: Data from homeless healthcare users, as outlined in SIHHC data variables in the 'Data Flow Diagram' document, including forename, surname, aliases, date of birth, sex, address, contact number(s), hospital of admission, date of hospital admission, nationality, ethnicity, and NHS number; from study fieldwork sites: November 2013 to a maximum of November 2016
- At each site the research team will create a unique study identifier for each record for the service provider. The data requested for the study will then be securely uploaded and processed at University College London (UCL). The data will be stored and cleaned. Identifiable information required by the Health and Social Care Information Centre (HSCIC) for the linkage to Hospital Episode Statistics/Office for National Statistics (HES/ONS) will at this point be transferred to HSCIC.
- When HSCIC have confirmed that the list is clean, and linkage to HES has been completed, the researchers will de-identify all data.

- Dataset 3: Data from homeless healthcare users, as outlined in SIHHC data variables in the 'Data Flow Diagram' document, including forename, surname, aliases, sex, address, and contact number(s); from Find and Treat Service: November 2008 to November 2016.
- The data requested for the study will then be securely uploaded and processed on the data safe haven at UCL. The data will be stored and cleaned. Identifiable information required by HSCIC for the linkage to HES/ONS will at this point be transferred to HSCIC.
- When HSCIC have confirmed that the list is clean, and linkage to HES has been completed, the researchers will de-identify all data.

- Dataset 4: Personal Demographics Service (PDS) data from homeless healthcare users, including date of hospital admission, date of hospital discharge, date of hospital appointment, and date of death: November 2008 to November 2016.
- The HSCIC will use data within PDS to provide missing NHS numbers for the two previous datasets. The research team will not at any point have access to these NHS numbers, which will be used to improve the linkage of data to HES.

- Dataset 5: HES ONS mortality data from homeless healthcare users and a geographically comparable and representative sample of lowest quintile of deprivation population in HES (based upon the index of multiple deprivation) equal in size to the Find and Treat dataset during the hospital admission study period: November 2008 to November 2016. This data will have already been de-identified by the HSCIC.

Amendment Request

The amendment request set out the following three changes to the project:

1. To extend the duration of support to the end of March 2019,
2. To revise the variables included within the analysis dataset, with the addition of four new variables and to exchange one item previously listed,
3. To revise the primary and secondary outcomes for the study.

Confidentiality Advisory Group Advice

The amendment requested was considered by the Vice-Chair, who recognised the delays experienced by the applicant in the receipt of data from NHS Digital which had led to the request to extend the duration of support required under the Regulations. The Vice-Chair was content to provide a recommendation to the extended duration of support. The Vice-Chair recognised that the wider amendments described did not impact on the scope of the support provided under the Regulations as the additional analysis variables were not considered items of confidential patient information.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Vice-Chair 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. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – UCL School of Life and Medical Sciences; published satisfactory reviewed grade at 66% on Version 14.1, 2017/18).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed).**

Group Members:

Name	*Notes*
Dr Tony Calland MBE	Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **UK National Screening Committee Hepatitis B in Pregnancy**

CAG reference: **CAG 7-04 (b)/2014 and CAG 5-07(b)/2013**

Context

Purpose of application

This audit application describes a collaborative project between University College London and the Immunisation, Hepatitis and Blood Safety Department at Public Health England (PHE) to look at outcomes for all at-risk infants.

A recommendation for class 4, 5 and 6 support was requested to cover UCL access to confidential patient information from NHS Trusts and PHE.

Confidential patient information requested

Data from NHS Trusts in relation to low risk women (previous application specified collecting this data for high risk women only) including:

- pregnancy outcome, i.e. termination of pregnancy, miscarriage, live birth or stillbirth
- date of pregnancy outcome
- NHS number for live born infants
- receipt of infant vaccination at delivery for live born infants

Around 2700 women fell within the low risk category; NHS number would be used to carry out data linkages. Infant date of birth was requested to establish timing of interventions in relation to delivery, and of the infant's subsequent immunisation schedule.

Amendment request

The amendment seeks an extension to the duration of support under the Regulations to the end of January 2019, to enable the completion of transfer of confidential patient information collated during the audit to Public Health England.

Confidentiality Advisory Group advice

The amendment request was forwarded to the Chair for consideration. The applicant had clarified that, following the transfer of the audit data to Public Health England, the ongoing retention of this data would be supported under Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002. From January 2019, following the transfer of confidential patient information to Public Health England, the applicants at University College London would complete the audit analysis on a

pseudonymised dataset. The Chair was content to provide a recommendation of support to the duration extension and acknowledged that the described exit strategy from support was appropriate. The applicant was reminded that, following the transfer of confidential patient information to Public Health England, should support no longer be required under this application reference, formal notification should be provided to enable the application to be expired.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – University College London, School of Life and Medical Sciences and Public Health England have a published satisfactory reviewed grade on V14.1, 2017/18**).

Group Members:

Name	*Notes*
Dr Patrick Coyle	Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Impact and Evaluation of a Burns Risk Assessment of Neglect and Maltreatment in Children Tool. BuRN-Tool A multi centre study**
CAG reference: **15/CAG/0203**
IRAS project ID: **169420**
REC reference: **15/WA/0259**

Context

Purpose of application

This research application from Cardiff University set out the purpose of the application to develop and test a Clinical Prediction Tool for use in the Emergency Departments (ED)/MIU'S (Minor Injury Units) and Burns Units to help identify features that may be significant when considering if a burn or scald is due to neglect or maltreatment. A further aim was to conduct a before and after study to evaluate the acceptability, efficacy and accuracy of the BuRNtool to identify maltreatment when implemented into clinical practice in Emergency Departments, Minor injury Units and Burns Units. Finally, a further aim was to identify if a version of the tool can be developed for use by child protection professionals.

The target range for this study are those aged 16 years and under. It was stated that patterns/types of thermal injury are unique to the developing child and it is vital that any safeguarding concerns are addressed especially in the younger children who are not able to verbalise what has happened to them.

A recommendation for class 1 and 6 support was requested to achieve the activities specified within the application and to enable a specific research nurse access to identifiable information. The applicant confirmed that the selection of feasibility study in the application was done in error, the application is for all sites.

Confidential patient information requested

Support was requested to allow the disclosure of confidential patient information from the BaSAT [form used to capture the related information]; on paper using the pro forma to the REDCap data base. Electronic data will be transferred from each centre, entered by the clinician onto the patient system (MEDWAY) at time of examination. The required fields are then transferred via secure download to the REDCap data base, this is overseen by NHS trust IT staff.

This would involve access to the following: Childs Medical record/Emergency department notes completed by the ED/MIU/Burn unit clinician (BaSAT); outcome of Safeguarding referrals (strategy meeting/case conference) from Children's Services. In particular, this would involve access to the following items: Name, NHS No, postcode at sector level to enable deprivation scoring, gender, ethnicity and date of birth.

Amendment Request

The amendment is seeking to change the items of confidential patient information processed for the purposes of the application activity. The following changes are proposed:

1. NHS Number is no longer required,
2. Postcode (already collected) will be used to identify the child's local authority,
3. In cases where name and date of birth (both already collected) were not sufficient to identify an individual child within the local authority system, address (not currently collected) will be used.

Confidentiality Advisory Group advice

The amendment requested was considered by the Vice-Chair, who was supportive of the required change to the items of confidential patient information which was required to facilitate the study linkage, as it had now been established that NHS Number was not used in the social care environment. The Vice-Chair was content to provide a recommendation of support to the use of full address to identify a child when name and date of birth were not sufficient. The additional use of postcode to identify a child's local authority was also accepted.

The Vice-Chair sought assurance that when the NHS Number was deleted, this was a secure destruction which could not be reinstated. The applicant confirmed that this was the case and provided details of the software package which would be utilised to destroy the records. It was noted that it was the applicant's responsibility to ensure that the mechanism of data destruction utilised was appropriate to securely and irretrievably destroy the items of confidential patient information which were no longer required. The Vice-Chair was content to provide a recommendation of support under the Regulations.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Vice- Chair 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. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – University of Cardiff, School of Medicine, Early Years Research Programme – Version 14.1, 2017/18 – published satisfactory reviewed grade**).
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed – 31 July 2018**).

Group Members:

Name	*Notes*
Dr Murat Soncul	Alternate Vice-Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Cellular Immunity to Herpesvirus infection: Studies with EBV & CMV**
CAG reference: **15/CAG/0127**
IRAS project ID: **143798**
REC reference: **14/WM/1254**

Context

Purpose of application

This application from University of Birmingham set out the purpose of investigating the way in which the human immune system, particularly a type of white blood cell known as a T lymphocyte, normally controls infection caused by two human herpes viruses, Epstein−Barr virus (EBV) and Cytomegalovirus (CMV). This study will inform the effects on patients who are immunosuppressed where viruses can cause more serious problem and also the immune response to EBV and CMV in patients with acute primary infection and in long−term healthy virus carriers. The outcome will support the development of future treatments of virus−associated disease in immunosuppressed patients.

A recommendation for class 3 and 6 support was requested to allow access to an authorised user for the purpose of selecting and contacting patients to seek consent.

Confidential patient information requested

Access was requested to seek support for the purpose of identifying a cohort of patients who tested 'monospot-positive' by the hospital haematology departments and to provide a member of the research team with patient name, date of birth and GP contact in order to seek consent from the GP and subsequently the patient, to participate within the study.

Amendment request

The amendment seeks a duration extension to the support recommended under the Regulations to 31 June 2023. The amendment also confirmed that the extended study duration was now funded by the Medical Research Council.

Confidentiality Advisory Group advice

The amendment requested was considered by the Alternate Vice-Chair who noted no issues with the proposed duration extension and was content to provide a recommendation of support for the amendment.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Alternate Vice-Chair 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. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – University of Birmingham, published satisfactory reviewed grade on V14.1, 2017/18**).
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed – 14 June 2018**)

Group Members:

Name	*Notes*
Dr Patrick Coyle	Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **The Role and Impact of Surgical Centralisation on Renal Cancer Survival: A Multifactorial Analysis**
CAG reference: **15/CAG/0169**
IRAS project ID: **185885**
REC reference: **15/EM/0340**

Context

Purpose of Application

This application from the University of Cambridge set out the purpose of a research study which aimed to link data from HES, ONS and Cancer Registries in order to answer five specific questions. First, how has nephrectomy practice in England evolved in the past few years in response to regionalisation? Second, what role does service reconfiguration play in changing renal cancer outcomes? Third, what is the relationship between case volume and outcome in nephrectomy, from short to long term and how does treatment in a high volume centre alter an individual's outcome compared to treatment in a lower volume centre? Fourth, what are the interactions between treatment setting, patient background and tumour characteristics in predicting renal cancer survival and mortality? Finally, how does understanding the volume outcome relationship in nephrectomy change the current paradigm on renal cancer service and risk prediction model?

A recommendation for class 1, 5 and 6 support was requested to cover access to confidential patient information from Public Health England in relation to patients undergoing a nephrectomy between 1998 and 2013 (approx. 112,000 patients)

Confidential Patient Information Requested

Access was requested to a dataset including date of death and date of birth.

Amendment Request

This amendment requested an extension to the duration of support in place for the application activity. The project had been originally approved for a two year period; however, the applicants explained that due to delay in obtaining the required data from Public Health England, analysis of the full dataset did not commence until January 2017, which was a 1.5 year delay on the original timeframe.

The amendment requested a one-year extension to the application of support under the Regulations for the use of potentially identifiable data from Hospital Episode Statistics and the National Cancer Data Repository. It was confirmed that all required data had already been extracted and received.

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Vice-Chair who acknowledged the delay the applicants had experienced in receiving the required data. The applicants had stated that the extension to support would enable them to continue processing the study data until the completion of the project. The Vice-Chair agreed that the rationale for the amendment was sound and recommended support for the one year extension.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Alternate Vice-Chair 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. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – University of Cambridge, School of Medicine, published satisfactory reviewed grade on V14.1, 2017-18).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Not applicable – original REC opinion stands as study duration has not been extended, acknowledged as a delay to project start).**

Group Members:

Name	*Notes*
Dr Tony Calland MBE	Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Outcomes of Drug Coated Balloon Angioplasty, A UK Real Life Experience from 2009 to 2015**
CAG reference: **17/CAG/0145**
IRAS project ID: **195002**
REC reference: **17/NW/0278**

Context

Purpose of application

This research application from Norfolk and Norwich University Hospital NHS Foundation Trust set out the purpose of investigating long terms outcomes of Drug Coated Balloon Angioplasty Treatment, a novel therapy as opposed to standard Drug Eluting Stent insertion. This could provide an important source of information for health professionals and patients to guide future clinical practice and research.

It is currently standard practice for drug eluting stents to be used, which lead to challenging long-term complications. Early studies with the alternative method of Angioplasty with Drug Coated had shown encouraging results in terms of overcoming these complications and leaving less of a permanent impact. This study would investigate outcomes of this method for all types of coronary artery disease from 01/01/209 to 31/12/2015 at this NHS centre, with an estimated cohort size of over 1000 patients.

Data from the Trust database would be linked with NICOR (National Institute for Cardiovascular Outcomes Research) data to enable recording of any follow-up events for at least 12 months following the procedure.

Identifiers would be disclosed to NICOR for this purpose – the data returned from NICOR would be pseudonymised.

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

Confidential Patient Information Requested

Cohort

Data from Norfolk and Norwich University Hospital NHS Foundation Trust in relation to patients who have received Drug Coated Balloon Angioplasty.

NHS Number, gender and date of birth would be disclosed to NICOR to obtain follow-up data.

NHS Number, gender and date of birth would also be disclosed to the direct care team at other hospitals, should a patient have had a repeat procedure at a different site.

Amendment request

The amendment seeks to extend the patient cohort included in the study – the proposal will now follow-up patients who were fitted with drug eluting stents, in order to compare the outcomes with the initial patient cohort, who were treated with drug-coated balloon. There is estimated to be 3,000 patients in the drug eluting stent cohort to be followed up. The same data flows and data items will be followed as currently supported in the project. It was explained that data in relation to the initial patient cohort was still pending from NICOR – the applicant advised that they were seeking support to follow-up the comparison cohort simultaneously to expedite the linkage process to enable analysis to commence.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair who recognised the delays which had been experienced by the applicant in receipt of data from NICOR. The Chair agreed that it was logical to request the data for the comparison cohort simultaneously due to time and cost efficiencies. There was a high public interest in undertaking the comparison between the two treatment cohorts.

The amendment also explained that the patient cohort would also be followed up via mortality information held within the hospital. The Chair recognised that this element of the amendment did not require a recommendation of support, as it did not involve a breach of the common law duty of confidentiality; however, it was agreed that this would be acknowledged within the outcome letter to reflect the wider dataset which will be made available for analysis.

The Chair was content to provide a recommendation of support to the amendment.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair 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. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed - Norwich and Norfolk University Hospital NHS Foundation Trust and NICOR (covered by Barts Health NHS Trust), both have published satisfactory reviewed grade on V14.1, 2017/18,**).
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed – 12 September 2018**).

Confidentiality Advice Team:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **WMUK Rory Morrison Registry**
CAG reference: **17/CAG/0107**
IRAS project ID: **222521**
REC reference: **17/LO/0166**

Context

Purpose of Application

This application from University College London Hospitals NHS Foundation Trust set out the purpose of the establishment of a research database focussing on Waldenstroms Macroglobulinaemia (WM), a rare blood cancer caused by genetic changes in the cells of the immune system (called B cells) which affects over 400 patients per year in the UK. The optimum way of treating this disease is under investigation, as new therapies become available, but a clear picture of the disease in the UK is lacking. The project intends to address this through the establishment of a robust database of patients which can be utilised in the improvement of patient outcomes. The database will be managed by Dendrite Ltd.

A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover activities as described within the application.

Confidential Patient Information Requested

Cohort

All patients with a diagnosis Waldenstroms Macroglobulinaemia (WM) or an associated condition who are patients at clinical sites registered with Dendrite as registry centres. It was identified that there would approximately 420 patients added to the registry over the next two years.

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

- Full name – for establishment of record and validation,
- NHS number –validation and linkage,
- Hospital ID – validation,
- Date of birth – linkage and analysis,
- Date of death – linkage, survival calculation and analysis,
- Gender – analysis,
- Ethnicity – analysis,
- Postcode (district level) – validation and analysis,
- Local hospital name and address – validation and analysis.

Amendment request

The amendment requested the inclusion of an additional five hospital Trusts as data sources for the registry. The additional sites were as follows:

- Torbay Hospital, Torbay and South Devon NHS Trust, Torbay TQ2 7AA,
- Christie NHS Foundation Trust, Manchester, M20 4BX,

- King's College Hospital NHS Foundation Trust, London, SE5 9RS,
- Bart's Hospital, Bart's Health NHS Trust, London, E1 8PR,
- Northwick Park Hospital, London North West University Healthcare NHS Trust, Harrow, HA1 3UJ.

These additional sites would be disclosing the same items of confidential patient information and supplementary clinical details to Dendrite Ltd, who were acting as processor and managing the registry.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team as the amendment did not describe any changes to purpose, scope or include extend access to confidential patient information beyond Dendrite Ltd. which was currently supported under the application as processor the Registry.

The additional Trusts, whilst new data sources for the Registry, would only be disclosing the same data items via data flows which were already supported. The applicant was advised that there was no further requirement to submit amendments to include additional data sources to the Registry, if the sites would be following the currently supported data disclosures. The CAG could be informed of these additional sources at the time of annual review.

Confidentiality Advice Team conclusion

In line with the considerations above, the Confidentiality Advice Team 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. The CAG should be informed at the time of annual review of any supplementary data sources which had been added to the Registry. This condition only applied where these supplementary sources provided the same information via the data flows which were currently supported by the CAG.
2. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – Dendrite Ltd. has a published satisfactory reviewed grade on V14.1, 2017/18**).
3. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed – existing REC approval extends to addition of new sites**)

Group Members:

Name	*Notes*
Dr Tony Calland MBE	Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **IBIS-II DCIS Trial**
CAG reference: **ECC 6-02(FT9)/2012**

Study title: **IBIS-II Prevention Trial**
CAG reference: **ECC 6-02(FT8)/2012**

Context

Application Summary

The applications set out details of blinded randomised placebo controlled trials with the primary endpoint being the development of histologically confirmed breast cancer, both invasive and non-invasive (i.e. including new or recurrent DCIS). These will be separately categorised as local recurrence (all ipsilateral disease), distant recurrence or new contralateral tumour. Breast cancer mortality will also be analysed.

Support was sought under the Regulations to enable patient participants to be flagged within NHS Digital in order to receive details of cause of death and relevant HES data on trial participants. This would involve linking name, NHS number, date of birth and postcode, collected with consent from trial participants, to obtain these datasets data. Data would be returned in a pseudonymised format using a unique trial participant number.

Amendment request

The amendment request was submitted to confirm that support was in place under the Regulations for the applicants to seek further follow-up information from the patient's GPs to supplement data provided by NHS Digital. This additional data linkage with patient's GPs had been queried by NHS Digital as part of the annual renewal of the data application for HES, cancer and mortality information, as this was not directly specified within the scope of support which was currently approved.

The initial applications were supported under the Regulations as it was determined that the consent provided by patients who participated in the trials was not valid for the ongoing follow-up via administrative datasets.

The applicant was asked to confirm within the approved application form where the supplementary linkage with patient's GPs had been specified. It was clarified that follow-up by GP records had not been specified within the initial submission, as the applicants had felt that the consent which had been taken from patients covered this process. It was explained that the supplementary follow-up via participant's GPs was understood to be covered by the point which stated that the study team would need to have access to the participant's medical records. A copy of the original consent form was provided for reference.

Confidentiality Advisory Group advice

The amendment request and supplementary supporting information was forwarded to the Chair for consideration. The Chair was sympathetic to the applicant's situation as it was recognised that the standards and specificity required within an application had understandably progressed in the intervening period since these applications were first considered. However, it was commented that the description provided within the historic application, and supplementary documentation, would not be considered to provide sufficient detail, by current standards, to describe the supplementary linkage with GP records. The Chair confirmed, on this basis, that it was appropriate to handle the request as a formal amendment and was content to provide a recommendation of support for this.

The applicant had informed the Confidentiality Advice Team that they intended to submit a refreshed application in the near future in respect of this study, due to a proposed change in the follow-up methodology. The Chair was informed of this intention and it was recognised that this revised submission would be gladly received to prevent any further future queries around the scope of support which was in place for the activity. It was recommended that this was received for review by April 2019.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair 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. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – Barts Cancer Centre have a published satisfactory reviewed grade on V14.1, 2017/18**).
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Not applicable – REC support already extends to follow-up via GPs**).