Health Research Authority

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

July 2018

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1. NEW AMENDMENTS

Reviewers:

Name	Capacity
Dr. Murat Soncul	Alternate Vice Chair
Ms. Kathryn Murray	Senior Confidentiality Advisor

Study title: **National Confidentiality Enquiry into Patient Outcome and Death**
CAG reference: **PIAG 4-08(b)/2003**

Context

Purpose of Application

This application from the NCEPOD set out the purpose of reviewing clinical practice and identifying potentially remediable factors in the practice of medical and surgical care. NCEPOD examines the quality of the delivery of care, not specifically cause of death; this is done by reviewing the provision of care and treatment and the management of health services. The commentary and recommendations made in each report are based on peer review of the data submitted to them. A recommendation for class 1, 4, 5 and 6 support was requested to achieve the purposes set out in the application.

Confidential Patient Information Requested

Information would be obtained from case notes. This included: NHS Number, hospital number, date of birth, gender, date of admission, source of admission, name of admitting clinician/operating clinician, date of discharge/death (if appropriate), date of procedure, type of procedure (OPCS code), diagnosis (ICD10 code (if relevant)). In addition, name and postcode where required (for ONS/HES outcome linkage only).

Amendment Request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes this year. This amendment covered the second which involved review of acute bowel obstruction. The methodology follows the standard retrospective case identification case note review as previous reviews, but the topic is new.

Confidentiality Advisory Group Advice

The amendment request was reviewed by the Alternate Vice-Chair who noted that the request was for an extension to apply the same methodology that had been previously used and for which the applicant already had support.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – National Confidentiality Enquiry into Patient Outcome and Death (NCEPOD), Version 14.1, 2017-18, reviewed grade of satisfactory confirmed by email 06/07/2018).**

Reviewers:

Name	Capacity
Dr. Tony Calland	Chair
Ms. Kathryn Murray	Senior Confidentiality Advisor

Study title: **National Confidentiality Enquiry into Patient Outcome and Death**
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Amendment Request

The amendment proposed a move to an online system in order to facilitate data collection via clinician questionnaire. It was explained that to date, questionnaires have been completed in paper format by clinicians, which are returned to the NCEPOD office to be scanned into a database. The paper questionnaires did not contain any confidential patient information and was linked to the case information in the NCEPOD database by 'NCEPOD reference number. The proposed online system would enable the collection of the same data, but will enable clinicians to login to a server which is based in the NCEPOD office. It was confirmed that there would be no confidential patient information disclosed via the questionnaire or stored in the host database.

Confidentiality Advisory Group Advice

The amendment request was reviewed by the Chair who noted that the data flows and data items would remain the same; however, it was recognised that the online data entry facility would improve data security and efficiency of collection. The Chair acknowledged that the online platform was the current technological standard for data collection and was content to provide a recommendation of support to the amendment.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – National Confidentiality Enquiry into Patient Outcome and Death (NCEPOD), Version 14.1, 2017-18, reviewed grade of satisfactory confirmed by email 06/07/2018).**

Group Members:

Name	Capacity
Ms. Clare Sanderson	Alternate Vice Chair
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **An extension of the Arnold Lodge Admission Cohort Reconvictions and Intervening Treatment (ALACRITy) study: 1983-2013**
CAG reference: **16/CAG/0117**
IRAS project ID: **178222**
REC reference: **15/EM/0378**

Context

Purpose of application

This resubmitted application from the University of Nottingham set out the purpose of continued monitoring of the outcomes of a vulnerable cohort in terms of mortality and rehospitalisation, add to understanding of the long-term outcomes of these patients. This application intended to supersede and replace the support already provided for under references PIAG 4-07 (t)/2002 and ECC 4-15 (b)/2009. The study will generate long-term follow-up data that will help to inform public debate, service planning and patient care. Other potential benefits of the study include making community services aware of the need to address the risk of suicide and physical ill health as well as reoffending, and quantifying statistical risks and timescales for reoffending in clinical populations. There is also a potential benefit in raising awareness in mental health services of potential adverse outcomes such as excess mortality, particularly by suicide

A recommendation for class 1, 4 and 6 support was requested to enable the relevant activities specified in the application.

Confidential patient information requested

The purpose of this application was to refresh the original two references, and to extend the follow-up period of the original Arnold Lodge cohort (1983-2003) by 10 years to a census date of 30th June 2013, and also to examine the admission characteristics and outcomes of a contemporary cohort (2003-2013) to the same census date of 30 June 2013. This will involve collecting data for those patients from 2003-2009 for whom, due to resources, were not collected during the previous extension, and for all patients between 2009 and 30th June 2013. The identifiers as specified in the application would include name, NHS number, date of birth, date of death, full address, hospital ID, GP registration, gender, ethnicity and age and would be required to enable linkages between different data sources.

- ONS Mortality data obtained from NHS Digital (i.e. date of death, cause of death, district of death, current district of registration). Death certificates will be obtained from the ONS up to 30 June 2013
- NHS records (i.e. dates and durations of hospital admissions, type of hospital unit, discharges) via HES will be used to calculate outcomes in terms of hospitalisation, readmission, time at risk in open or community settings, loss to follow-up and physical health.
- The study sample will include all first admissions to Arnold Lodge MSU between July 1983 and 30th June 2013 (a period of 30 years). The follow-up nature of the project means that two subsets of patients will be identified: 1) patients in the original cohort admitted to Arnold Lodge between July 1983 and 30th June 2003 (n = 595, Set A); and 2) patients admitted to Arnold Lodge between 1st July 2003 and 30th June 2013 (n = estimated at 400, Set B).

- Patients in Set A require follow-up/outcome data collection for the additional time period 1st July 2003 to 30th June 2013. Patients in Set B will require full admission and outcome data collection from clinical records held at Arnold Lodge from 2003-2013. Admission data are already available for a subset of Set B patients, those admitted between 2003 and 2009, collected as part of an extension to the original study. Data collection ended due to limited resources and so this new study will complete the data collection for the remaining patients in the cohort.
- Admission data will be obtained from medical records at Arnold Lodge. Outcome data will be obtained from: clinical records at Arnold Lodge and other mental health services(both part of Nottinghamshire Healthcare NHS Foundation Trust and other Trusts where possible), the Mental Health Casework Section (for patients on restriction orders of the Mental Health Act), Office for National Statistics (ONS, part of NHS Digital for mortality data, the General Practitioners registration database, the Police National Computer (reconvictions
- General Practitioners, both in the community and in prison, and consultant psychiatrists who may be identified as having had some contact with former patients over the course of the follow-up period with be contacted via post to provide details regarding service contact.

Amendment Request

The amendment requested support for the following three changes:

1. Change of main applicant – the current named applicant, Professor Birgit Völlom, is leaving her post and will be replaced by Dr Simon Gibbon,
2. Extension to the duration of support – due to delays in the receipt of data from NHS Digital, the applicants are seeking an extension to support to 31/12/2018,
3. For information – patient-facing information has been updated following the implementation of the General Data Protection Regulations at the request of by NHS Digital.

Confidentiality Advisory Group Advice

The amendment request was shared with the Alternate Vice-Chair for review. It was acknowledged that the suitability of the new Chief was an assessment which would be undertaken by the REC and confirmation of the favourable ethical opinion had already been received with respect of this application. The Alternate Vice-Chair was content to provide a recommendation of support to this element of the amendment on the basis of the REC assurance.

It was recognised that the applicant had informed the CAG of the delays encountered in receiving data from NHS Digital within the 2017 Annual Review. As such, an amendment to extend the duration of support under the Regulations had been anticipated for the project. The Alternate Vice-Chair was content to provide a recommendation of support to the extension up to 31 December 2018. Should it become apparent that a further extension to the duration of support in place is required; the applicant was reminded to submit the associated amendment in a timely fashion, ideally at least six weeks in advance of the expiration of current support.

The revised information materials were received and noted and no further issues were raised.

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 – Nottinghamshire Healthcare NHS Foundation Trust, Version 14.1, 2017/18**).

2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed – 19 June 2018**).

Reviewers:

Name	Capacity
Dr. Tony Calland	Chair
Ms. Kathryn Murray	Senior Confidentiality Advisor

Study title: **Risk modelling for quality improvement in the critically ill: making best use of routinely available data**
CAG reference: **15/CAG/0163**
REC Reference: **15/WA/0256**
IRAS ID: **172505**

Context

The application from the Intensive Care National Audit & Research Centre (ICNARC) sets out the purpose of conducting an epidemiologic study to understand the risk factors for, and the consequences of critical illness leading to improvement in risk models used to underpin national clinical audits for adult general critical care, cardiothoracic critical care and in-hospital cardiac arrest by utilising data linkage with other routinely collected data sources. The patient cohort would include patients admitted to an adult critical care unit or experiencing an in-hospital cardiac centre in NHS Hospitals in England and Wales for the period between 1st April 2009 to 31st March 2015.

The applicant received s251 support in order to disclose confidential patient information to the Health and Social Care Information Centre (HSCIC) and also for the HSCIC to carry out data linkage activity to link datasets from Case Mix Programme (CMP), the National Cardiac Arrest Audit (NCAA), National Diabetes Audit, UK Renal Registry and National Adult Cardiac Audit with Mortality data from the Office for National Statistics and also HES Data from NHS Digital.

Amendment Request

Due to delays in processing of the application to NHS Digital for data linkage with HES and ONS data and to access data from the National Adult Cardiac Surgery Audit the research study is running behind schedule. The amendment sought an extension to support up to 31 December 2018.

The amendment will allow the objectives of the project to be achieved. Without this extension, the proposed project would not be able to be completed.

Confidentiality Advisory Group advice

This request was considered by the Chair, where it was agreed that the request appeared reasonable. The rationale for the duration was noted to be caused by delays in processing of the application by NHS Digital. Support was recommended for the amendment.

Confidentiality Advisory Group conclusion

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

Specific Conditions of Support

1. Favourable opinion from a Research Ethics Committee (**Confirmed – REC review is not required for an extension to study end date**).

2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – ICNARC, reviewed satisfactory grade on V14.1, 2017/18**).

Reviewers:

Name	Capacity
Dr. Tony Calland	Chair
Ms Clare Sanderson	Alternate Vice-Chair
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **A randomised controlled trial to evaluate invitation to community-based low dose computed tomography (LDCT) screening for lung cancer versus usual care in a targeted population at risk.**

CAG reference: **18/CAG/0038**

IRAS project ID: **235803**

REC reference: **18/NW/0012**

Context

Purpose of Application

This application from the Leeds Teaching Hospitals NHS Trust set out the purpose of medical research which aims to test targeted Low Dose Computed Tomography (LDCT) scans screening in community settings concentrating on deprived areas of Leeds. The intention is to randomise 55-80 year old smokers or ex-smokers to intervention or usual care groups prior to approach. The intervention group will be invited to assessment for a Lung Health Check (including LDCT screening for high-risk people) framed as a pilot health service.

The applicants intend to compare outcomes between the invited group and a usual care group, which won't be invited to take part or know that they are in a research study. By comparing outcomes with a control population, the true benefits (of reducing number of late stage cancers, and therefore lives saved) and possible harms (of over-diagnosis) of introducing screening in the UK will be assessed.

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

Confidential Patient Information Requested

Cohort

Smokers or ex-smokers, aged between 55-80 years old, who are judged to be at increased risk of lung cancer as estimated by three criteria within the Leeds CCG area. There a wider range of clinical inclusion/exclusion criteria which would need to be satisfied before a patient would be invited to participate.

The cohort will consist of 62,980 people randomised, of which the following is anticipated:

- 31,490 people allocated to the intervention arm to receive an invitation to a Lung Health Check LDCT screening (including LDCT screening for people at high risk of lung cancer)
- 31,490 people allocated to the control arm who will not be approached but are necessary to follow study outcomes
- 6,892 people attending for lung health check and undergoing LDCT screening

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

- Name – to invite participants, deleted after invitation process,
- Patient Address including postcode – for invitation process and retained for ensure validity of randomisation (audit to be undertaken 6 months from randomisation then deleted),
- Postcode – converted to index of multiple deprivation and retained for analysis,
- NHS number– validation of sample, identification and linkage and long-term follow-up,
- Date of birth – linkage and analysis and retained for long-term follow-up,
- Date of Death – analysis – full format,
- Cause of Death – received in ONS coded format,
- Postcode – analysis (Deprivation score) and intervention arm (facilitate invitation) and retained for all to facilitate long-term follow-up,
- Gender – analysis and retained for analysis,
- GP Registration (practice) – required for invitation process and retained for analysis,
- Named GP – required for invitation process and then deleted,
- Ethnicity – analysis.

Amendment Request

The amendment outlined the following three revisions to the study:

1. **Change to individuals accessing and extracting confidential patient information from GP practice databases.**

The applicants are seeking to extend support to enable a wider group of individuals to undertake the data access and extraction processes at GP practices, in order to identify patients who were eligible for invitation to the trial. Specific roles had been identified within the research team, which were the Project Manager, Data Manager, Lead Nurse and Contributing Consultants and the West Yorkshire Research and Development team who are able to assist with this data extraction.

2. **Inclusion of an additional exclusion criteria**

The applicants are proposing an extension to the trial exclusion criteria to include those patients who were resident in a nursing home.

3. **Change to Data Transfer Methodology**

It was explained that data transferred from GP practices to the Leeds Institute for Data Analytics (LIDA) within the University of Leeds and Leeds Teaching Hospitals NHS Trust will now be transferred via the Biscom transfer system, rather than the previously described N3 connection.

Confidentiality Advisory Group Advice

The amendment request was considered by a Sub-Committee of the Confidentiality Advisory Group.

Members were content with the rationale provided to support the exclusion of care home residents from the trial, as it was agreed that there were multiple reasons why a patient may be resident in a nursing home, which would make trial suitability difficult to ascertain.

The applicants had provided confirmation that revised data transfer system was already covered within the NHS IG Toolkit submissions referenced within the application. The CAG was content that the relevant assurance had been provided by NHS Digital in relation to the toolkits and no further issues were raised in this area.

The Group considered the applicants request to extend the scope of support to include a wider group who were able to undertake the patient identification activities within GP practices. The time pressures on the

recruitment process were recognised to ensure that eligible patients, who were invited to participate, were actually able to attend the lung screening vans to undergo the trial appointments. The applicants explained that the Clinical Research Network, which had previously agreed to resource the research nurses required to undertake the recruitment procedures at GP practices, was no longer able to guarantee the resource, due to staffing issues.

The Group was satisfied that the rationale provided supported the amendment and Members were content to provide a recommendation of support to the wider members of the research team undertaking this activity, as it was acknowledged that these individuals all had substantive or honorary contracts with the Trust and were bound by the appropriate confidentiality requirements in relation to patient data. The CAG was unclear about the role of the Research and Development staff who had also been cited within the amendment application and further details were requested from the applicants in relation to these individuals.

In response to the queries raised by the Sub-Committee, the applicants explained that in the intervening period since submission of the amendment, they had undertaken training within the GP practice environment in relation to how the systems worked and the requirements of carrying out the search procedures necessary for the trial recruitment procedures. The applicants advised that, having subsequently understood how straightforward the procedure was, they were now confident that this activity could be undertaken by the proposed members of the research team. The request to extend support to Research and Development staff was rescinded by the applicants.

Members received the response and were content to provide a recommendation of support for the amendment on the basis that the recruitment procedures would be undertaken by members of the research team, with assistance from the previously supported research nurses provided by the CRN, where available.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

1. Support is extended to enable named roles within the research team (Project Manager, Data Manager, Lead Nurse and Contributing Consultants) to access GP patient records in order to facilitate the patient identification activities required for the trial recruitment.
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed – 20 July 2018**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed)**
    - **Leeds Teaching Hospitals, organisation code RR8, Reviewed grade satisfactory (v.14.1 2017-2018).**
    - **University of Leeds – IRC, organisation code 8E218-IRC, Reviewed grade Satisfactory (v14.1 2017-2018).**
    - **CFH Docmail LTD, organisation code 8HN70, Reviewed grade Satisfactory (v14.1 2017-2018).**

Reviewers:

Name	Capacity
Dr. Tony Calland	Chair
Ms. Kathryn Murray	Senior Confidentiality Advisor

Study title: **Hip Fracture Audit**

CAG reference: **CAG 8-03(PR11)/2013**

Context

This audit application received approval by the Secretary of State for Health on 11 April 2011. The application set out aims to use case-mix, process and outcome data together with quality standards to improve the quality of care. The audit was administered by the Royal College of Physicians (RCP) as data processor on behalf of HQIP.

A recommendation for class 1, 3, 4, 5 and 6 was requested to cover linkage with Hospital Episode Statistics (HES) data. Access was requested to NHS number, date of birth, date of death and postcode.

Amendment Request

The amendment proposed set out a proposed linkage between the National Hip Fracture Database and the National Joint Registry in order to explore the use of total hip replacement. It was explained that the Royal College of Physicians had been commissioned to carry out linkage between the National Hip Fracture Database (data controller HQIP; data processors: RCP, Crown informatics) and the National Joint Registry (data controller HQIP, data processor Northgate Public Services), in order to explore the use of the 'total hip replacement' for hip fracture.

This will involve the transfer of confidential patient information from the National Hip Fracture Database (NHFD), held by from Crown Informatics to Northgate Public Services. The following data items would be transferred to facilitate linkage:

- NHS number,
- Forename,
- Surname,
- DOB,
- Postcode.

This will be supplemented with the following additional clinical data items:

- Date and time of admission,
- admitting hospital,
- date and time of operation,
- procedure type.

The patient cohort to be included would patients with a record of total hip replacement within the database since 2011.

Northgate would subsequently link the NHFD data to the National Joint Registry (NJR) data for the same period and provide an assessment of the extent to which the two databases describe the same cohort of patients. The proposed data linkage would be undertaken on a one-off basis.

Confidentiality Advisory Group Advice

The amendment was considered by the Chair. The applicants were asked to clarify the approximate patient sample size, as this was unclear from the detail included within the amendment submission.

It was explained that an exact cohort size could not be confirmed without undertaking an extraction from the audit database; however, it was estimated that around 5,000 patients underwent total hip replacement each year. It was explained within the amendment submission that there was currently no mechanism to monitor/audit in terms of specific approaches to total hip replacement after hip fracture. The NICE's 2016 update turned on an economic model which viewed all total hip replacement types/components as equivalent, despite differences in their cost and survival. It was clarified that the National Hip Fracture Database's role as the lead mechanism for auditing compliance with this aspect of NICE would also be further complemented by the detail contained in the National Joint Registry.

The clarification was received by the Chair, who acknowledged that the current amendment would test the feasibility of undertaking linkage between the two audit databases as a first step but was assured that there was public interest in progressing linkage between the established datasets. The Chair was content to provide a recommendation of support to the amendment.

Confidentiality Advisory Group Advice 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 - Royal College of Physicians (8J008-CSD), Crown Informatics (8J157) and Northgate Public Services (NWY) all report a reviewed satisfactory grade on V14.1, 2017/18).**

2. APPLICATIONS

Reviewers:

Name	Capacity
Dr Tony Calland MBE	Chair
Dr Rachel Knowles	CAG Member
Dr Harvey Marcovitch	CAG Member
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **NHS Improvement Getting It Right First Time (GIRFT) programme**
CAG reference: **18/CAG/0072**

Context

Purpose of Application

This application from NHS Improvement set out the purpose of service evaluation to determine the specific causes of medical negligence claims with surgical specialities through detailed case analysis. The programme aims to identify poor practice and influence national guidance to address to reduce the number of claims and improve patient care and experience of the NHS.

The purpose of the Getting It Right First Time (GIRFT) programme is to determine specific causes of clinical negligence claims against all NHS services from both medical and surgical specialities as well as all areas in which NHS Resolution receive claims in order to improve patient care. The GIRFT programme will also monitor the volume and cost of these claims to drive service improvements. The previous approved programme had looked solely at surgical specialities.

The updated GIRFT programme would like to access specific litigation data held by NHS Resolution on its claims management system. This reflects the Secretary of State for Health and Social Care extending the remit of the programme, as part of the Lord Carter recommendations, to include over 34 specialities, both medical and surgical, and the role that both NHS Improvement GIRFT and Model Hospital teams are to play in order to help NHS Resolution and NHS trusts learn from claims.

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

Confidential Patient Information Requested

Cohort

- All individuals who have notified NHS Resolution of an intention to make a claim against an NHS Trust since 01/01/2003 to 31/12/2020.
- An accurate sample size cannot be estimated from the outset of the project; however, it is stated that 57,761 claims have been made in the last five years alone.

The following items of data will be released from NHS Resolution to NHS Improvement:

- Patient age at incident,
- NHS Resolution Claim Reference and Claim ID,

- Sex,
- Description of medical negligence claim including dates of incident, date of case creation (notification), case status and outcome, damages paid, case costs, causes and injury sustained.

Confidentiality Advisory Group Advice

A Sub-Committee of the CAG reviewed the applicant's written response to the previous request for additional information, as detailed in the previous provisionally supported outcome, in correspondence.

1. **Confirm that the 'Patient's Age at Incident' field would be provided in years or months only.**

The applicants confirmed that this would be provided in years only.

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

2. **Confirm that the data extracts provided by NHS Resolution would not include any information in relation to third parties. Alternatively, provide clarification of the alternative legal basis under which the data relating to third parties would be disclosed.**

The applicants confirmed that the data would be cleansed prior to its release to NHS Improvement to ensure that no information in relation to third parties is included.

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

3. **Patient and Public Involvement and Engagement – further work is required in this area to address the following points:**
    a. **An overview of planned involvement and engagement activity with an appropriate group of patients and the public to discuss the programme and the use of patient data, should be provided to explain how work would continue in this area as the programme proceeded,**
    b. **Provide further clarification around the engagement with the Patient's Association, to clarify whether there is wider involvement outside of the executive team,**
    c. **Activity in this area should include discussions around how the communication strategy for the project can be strengthened in order to raise the profile of this activity,**
    d. **It is recommended that appropriate charities are approached about the programme – feedback should be provided around this element,**
    e. **If the responses given were negative, the CAG would take this into account when considering whether support can be recommended for the activity.**

The applicants explained that they would continue to work with the Patient's Association. It was explained that the applicants had recently met with their newly appointed CEO, who had agreed to provide a statement of support for this programme from the Board and to continue to look into the options for providing direct patient engagement with the programme. It was explained that the Patient's Association continued to be very supportive of this work and were keen to support GIRFT moving forward.

The applicants explained that, at the next meeting, they would be asking the Patient's Association to work with them and assist in advertising and recruiting to a volunteer group that could engage with NHS Improvement on this project to ensure appropriate support for this activity. The applicants confirmed that they would provide updates around progress and an agreed plan of action once this group had been established. Key areas which would be covered would include a request for feedback around the proposed communications with the public and the right to opt out and how the profile of the activity can be raised to ensure individuals are aware of their rights and the use of their personal data.

The applicants provided a clear steer that they would not interact with 'Action Against Medical Accidents' AVMA to support this work as it was stated that this charity consistently expressed views in the national

media which were contrary to the ethos of our programme. A link to a BBC radio programme was provided to support this view.

The Sub-Committee considered the response provided by the applicants in this area and it was agreed that whilst activity (planned and undertaken) was limited in this area, Members were content to provide a recommendation of support to the application activity with specific conditions to progress work in this area. It was agreed that an interim report would be required within three months of support coming into effect which would provide an update from the further scheduled meeting with the Patient's Association and to confirm the establishment of the volunteer group together with an overview of its demographics and confirmation of the first meeting date.

The Group agreed that details of the volunteer group terms of reference would be required to understand how regularly they would meet, how the role and remit of the group was defined and to confirm how frequently they would receive feedback from the programme team to enable views to be gathered.

Members recognised the applicant's confirmation that the volunteer group would be asked to consider the communication materials and established objection mechanism for the programme. It was agreed that feedback from this engagement would be required, together with any resulting revised communications strategy and supporting documentation for consideration.

4. **Provide an overview of how and by whom a mechanism to respect patient objection to the use of their data would be operated for the project. Provide copies of any revised or supplementary documents which support this for information.**

The applicants clarified that reasonable measures would be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate via NHS Improvement and NHS Resolution fair processing notices. The NHS Improvement notice was updated to provide details around how an objection could be raised to the processing of data. It was confirmed that any requests to opt out of the GIRFT processing activities would be respected and confidential patient information would be deleted from all data held within the NHS I data warehouse and disaster recovery centre. All other accompanying litigation data would remain in the database.

The Sub-Committee received the response and the revised notification material. Members reiterated that engagement with the volunteer group were key in this area to ensure that information materials and right of objection were clear and accessible to patients and the public.

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, 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 – an interim report is required within three months of the date of this letter to provide an update on feedback in this area. This should address the following points:
    a. Provide an overview of discussions/activity at the further scheduled meeting with the Patient's Association,
    b. Confirm the establishment of the volunteer group to support the project and provide an overview of the demographics of the group and the first scheduled meeting date,
    c. Terms of reference for the volunteer group should be provided to explain the role and remit of the group, how regularly meetings would be scheduled and how frequently feedback would be provided by the programme,

d. The group should be approached to consider the patient notification and dissent materials and be asked to provide comments on their suitability for a wide patient audience. Feedback should be provided together with any documentation which has been revised for review,
e. If the responses given are negative, the CAG would take this into account when considering whether support can continue or whether further action is required.

2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – NHS Digital's reviewed grade on Version 14.1, 2017/18 for MONITOR (encompassing NHS Improvement) received via email on 07/06/2018).**

Group Members:

Name	Capacity
Professor William Bernal	CAG Member
Dr Tony Calland MBE	Chair
Mr Anthony Kane	CAG Lay Member
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **Development and Validation of Barts Heart Centre Surgical Infection Risk (B-SIR) Tool to Predict Surgical Site Infection After Cardiac Surgery**
CAG reference: **18/CAG/0080**
IRAS project ID: **241144**
REC reference: **18/WA/0159**

Context

Purpose of Application

This application from Barts Health NHS Trust set out the purpose of medical research which aims to develop an assessment tool that will help identify patients at risk of developing surgical site infections after cardiac surgery. The study also aims to compare the new tool with the other risk assessment tools. Surgical site infections are serious complications following surgery which can lengthen a patient's stay in hospital and increase the risk of morbidity and mortality.

The applicants will be undertaking a retrospective case note review of patients who underwent a coronary artery bypass graft (CABG) and/or valvular surgery at the Barts Heart Centre between January 2016 and December 2017, who meet the study inclusion criteria. Wider clinical information will be collated from locally held records of data which were prospectively collected for submission to the following audits/surveillance activities: Intensive Care National Audit and Research Centre (ICNARC), National Institute of cardiovascular Outcomes Research (NICOR) and Public Health England (PHE) SSI Surveillance.

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

Confidential Patient Information Requested

Cohort

Patients underwent a coronary artery bypass graft (CABG) and/or valvular surgery at the Barts Heart Centre between January 2016 – December 2017. This will be established from a search of the locally held SSI Surveillance register at Bart's Heart Centre. It is estimated that 2,000 patient records will be included.

The following items of confidential patient information are requested for the purposes of linkage between the three datasets:

- Medical Record Number/Hospital Number,
- Date of birth,
- Date of surgery.

Confidentiality Advisory Group Advice

The Sub-Committee considered the applicant's written response to the request for further information outlined in the provisionally supported outcome in correspondence.

Supplementary Background Information

The applicants had provided some additional information within the response which further outlined the purpose of the project. The applicants explained that the purpose of the application was to undertake a secondary analysis of local data collected and submitted to three national audits between 2016 and 2017 (Intensive Care National Audit and Research Centre, National Institute for Cardiovascular Outcomes Research and Public Health of England SSI Surveillance), all of which operated with CAG support for patient data to be used for audit purposes without patient consent. The applicants explained that they were seeking a recommendation of support from CAG to use this data without patient consent for research purposes, to develop and validate a model of identifying patients at risk of developing a surgical site infection after cardiac surgery.

The applicants explained that confidential patient information would be used only to link the data from the three datasets following which all patient identifiers would be removed leaving an anonymised dataset for analysis purposes. The applicants explained that seeking patient consent could introduce bias as patients not consenting or unable to be contacted (the patients are not current patients at our hospital) may be the ones who experienced a wound complication and thus, the developed risk model would be flawed. The applicants further stated that the proposed study intended to work on the same premise as NICOR research application (CAG ref 17/CAG/0078), which was why the application had been made to the CAG.

Members of the Sub-Committee considered the additional information. It was noted that surveillance activities undertaken by Public Health England were enacted under Regulation 3 of the Health Service (Control of Patient Information) Regulations. To ensure that the legal basis under which the three source datasets was collated was accurately referenced, it was clarified that the PHE SSI surveillance was a Regulation 3 activity and as such, had not been considered by the CAG.

It was confirmed in the provisionally supported outcome that the Group was assured by the applicant's rationale to justify why consent was not feasible for the project so no further consideration of this element was required.

The Sub-Committee noted the reference to the NICOR Extended Use of Data application (17/CAG/0078); however, the relevance of this was unclear as the cited application was an established research database created from the data collated via the audit programme. The proposed application was for a specific research project which was why there was a requirement to understand the acceptability of using confidential patient information which had been collected for different purposes in order to achieve the project aims and also to establish a communications strategy which would inform the relevant patient population of how the specific dataset would be processed and used for these additional purposes. Further consideration was given to these requirements from the applicant's formal response detailed below.

1. **Patient and public involvement and engagement activity should be undertaken to test the acceptability of using confidential patient information without consent for the study purposes. Feedback should be provided around what activity was carried out and the feedback provided as part of this. 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.**

The applicants clarified that the cardiac surgery patient group had originally identified the need for research to improve patient care relating to surgical wound infections after cardiac surgery. It was further

explained that the applicants had sought the views of this group around the appropriateness of using already existing data without patient consent for this purpose. The reported outcomes of this interaction showed 89% of people asked were in support of the proposal with one patient being opposed; however, no justification had been provided to support this negative response. The applicants further explained that by using the existing data there was no risk to individual patients and all confidentiality and information governance requirements would be adhered to.

The Sub-Committee was assured by the response and raised no further queries in this area.

2. **Patient Notifications and Dissent – further work is required in this area to address the following points:**
   a. **A communications strategy for the study should be designed, to include outpatient posters and a website notification as a minimum. The information materials should include an opt-out mechanism. Copies of the documentation should be provided for review by the CAG,**
   b. **An overview of how the objection mechanism would be operated is required,**
   c. **Seek clarification from the Trust around whether there is any scope to check for evidence of historic dissent recorded by patients on an electronic system and provide to confirm whether this would be possible.**

The applicants explained that the patients who would be included in the project were no longer active patients as they had undergone surgery in 2016-2017 and had now been discharged from our care. For this reason, the applicants explained that they were unclear of the rationale and value of a communications strategy to include outpatient posters and website notification for patient notifications and dissent.

The applicants acknowledged that patients may have withdrawn from the national datasets. Contact was made with the data managers for the NICOR and ICNARC audit programmes who had confirmed that there had been no requests for the removal of data from the database. Information was provided around the opt-out arrangements for these programmes.

The applicants recognised the importance of communicating and disseminating the study results to patients and agreed to design a plan to support this with the involvement of the cardiac surgery patient group.

The Sub-Committee received the response and agreed that the display of information within the outpatient clinic was not appropriate in this instance. The Group also agreed, in light of the further information provided, that the established dissenting mechanisms for the NICOR and ICNARC programmes were sufficient for the purposes of this project. Members did however agree that, in the interests of transparency and promoting how confidential patient information was being used for research purposes, information about the study should be displayed on the Trust website as it was noted that this displayed information in relation to featured ongoing studies. It was agreed a copy of the text, together with confirmation that this had been published would be required within three months of support coming into effect. Members agreed that feedback could be provided at the time of first annual review in relation to the communications strategy which had been established in conjunction with the patient group, for the research findings.

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. The study should be promoted on the Trust website – confirmation that this has been actioned, together with a copy of the text, should be provided within three months of this date of this letter.
2. Work should be undertaken with the Cardiac Surgery Patient Group to devise a strategy to share the research findings with patients – an update around this work should be provided at the time of first annual review.
3. Favourable opinion from a Research Ethics Committee **(Confirmed – 04 July 2018)**.
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed – Barts Health NHS Trust shows a reviewed satisfactory grade on V14.1, 2017/18).**

Reviewers:

Name	Capacity
Dr Malcolm Booth	CAG Mermber
Dr Patrick Coyle	Vice Chair
Professor Jennifer Kurinczuk	CAG Mermber
Mrs Diana Robbins	Lay Member
Mr Marc Taylor	CAG Mermber
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **A critical evaluation of community based integrated care policy**
CAG reference: **18/CAG/0087**
IRAS project ID: **219628**
REC reference: **18/EM/0084**

Context

Purpose of Application

This application from the University of Essex set out the purpose of medical research which aims to determine how national policy discourses underpinning community based integrated care have been enacted as programme resources designed to create behaviour change in health professionals and service users. Secondly, the study will aim to evaluate to what extent these programme resources have been successful at meeting both policy maker's aims and creating changes to wider structures. The aim of the research is to conduct a critical evaluation of community based integrated care policy by first of all determining the way in which the local implementers (CCG, County Council, Lead Provider) have re-contextualised and enacted national policy discourses in the form of discursive and material programme resources. The applicant will be undertaking interviews with patients and various members of staff delivering care, as well as undertaking observations of the multidisciplinary teams who deliver community-based care.

The project has a number of elements which are out of scope for the CAG review. The two elements which the CAG is being asked to consider are the day-to-day office observations and the recordings of multi-disciplinary meetings. The research aims and outcomes do not require confidential patient information; however, it is acknowledged that the applicant may be incidentally exposed to information of this type when observing health care professionals delivering their work.

The applicant will undertake 140 hours of participant observation within the multidisciplinary team offices. This will be split across the four integrated care teams and will involve 35 hours of observation in each office. The main applicant will hot desk in the office, in order to blend into the office environment. No confidential patient information would be recorded by the Chief Investigator, as part of her field notes.

Non-participant observation of eight complex case review multidisciplinary team meeting (two meetings per integrated care team), which include members of external agencies, such as GPs, social workers, and mental health professionals will be carried out. The meeting would be video-recorded without the main applicant being present. The reason for this approach is to capture highly valid data that can be subject to detailed sociolinguistic analysis that accounts for body language, as well as verbal communication. The main applicant would be there at the beginning and end of the meeting to set the video recorder up. The Chair of the meeting will briefed on how to pause and restart the recording if

sensitive information was being discussed that they did not want to be recorded. These observations will take place in the Multidisciplinary Team offices where the meetings are held. The main applicant will transcribe the video recording on site, so no confidential patient information would be transferred offsite. The applicant would not transcribe any confidential patient information from the recordings.

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

Confidential Patient Information Requested

The applicant will be observing:

- Health Professionals contained with multidisciplinary teams, internal to the community based integrated care provider (nurses, physios, OTs).
- Professionals belonging to external partners who are involved in multidisciplinary team meetings (GPs, social workers, mental health professionals)

The applicant is not seeking access to any confidential patient information; however, it has been identified that this may be disclosed incidentally during the course of the observations with staff.

Confidentiality Advisory Group Advice

The Chair considered the applicant's below written response to the request for further information outlined in the provisionally supported outcome in correspondence.

1. **Confirm whether the patient PROMS information which will be provided from Sky Blue will relate to the patients under the care of the health care providers being observed and/or discussed at the MDT meetings. If so, clarify how this relevant linkage will be performed.**

The applicant confirmed that no data linkage would take place between the data obtained in the observations (meetings and office space) and the PROMs data supplied by Sky Blue. The analysis would be conducted separately.

The response was received and no further issues 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 Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support (Final)

1. The planned patient and public engagement activity should proceed, which should include discussion around the communications strategy and patient dissenting mechanism for the study. Feedback on the outcomes of this activity should be provided within six months of final support coming into effect. If the responses given are negative, the CAG would take this into when considering whether support can continue, or if further action is required.
2. Patient Notifications and Dissent – a communications strategy should be developed for the study, including a meaningful dissenting mechanism. An overview of how and where information would be displayed, together with copies of any documentation, would be required as part of the six month interim report.
3. Favourable opinion from a Research Ethics Committee (**Confirmed – 26 March 2018**).
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Anglican Community Enterprise (Social**

Enterprise) – satisfactory reviewed grade on V14.1, 2017/18 by NHS Digital email on 03/07/2018).

Reviewers:

Name	Capacity
Dr Malcolm Booth	CAG Member
Dr Patrick Coyle	Vice Chair
Professor Jennifer Kurinczuk	CAG Member
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **Breast Cancer (BC) Predict - Providing breast cancer risk as part of the national breast cancer screening programme: building an evidence base on benefits and harms to inform a decision to implement**
CAG reference: **18/CAG/0082**
IRAS project ID: **239199**
REC reference: **18/LO/0649**

Context

Purpose of Application

This application from the University of Manchester set out the purpose of medical research which aimed to automate the breast cancer risk estimation process to assess feasibility of rolling this out more widely as part of the NHS Breast Screening Programme.

The National Institute for Health and Care Excellence (NICE) states that women at high-risk of breast cancer should have more frequent breast mammography (x-ray) screening and be offered risk-reducing treatment with the medicines tamoxifen, raloxifene or anastrozole. However, women at increased risk of breast cancer in the NHS Breast Screening Programme (NHSBSP) cannot be offered prevention drugs or extra screening as the screening programme does not currently estimate or inform women of their risk.

A proportion of women attending breast screening will be invited to join the study. Those opting to participate will join via online consent, following which they will complete the online breast cancer risk estimation tool. Women may also opt to have a mammogram, though this is not compulsory. Those who have a mammogram will have breast density assessed from the mammogram and this will be combined with the information they provide in the online questionnaire to estimate their breast cancer risk. Risk information will be sent to participants via letter after confirmation of a normal mammogram result (approximately 6-weeks after consent).

There are three elements to the study which required support under the Regulations which include Phase 1 of the proof of principle – in which women attending on the day for a mammogram will be invited to participate in order to test the systems. Phase 2 of the proof of principle will be initiated once the initial phase has tested that the study processes work and will test whether these work optimally and confirm that there is no requirement for a control group. Following this, the main study will be initiated across the three areas.

Women will be recruited from three NHS Breast screening programmes: Greater Manchester (Withington Community Hospital, Oldham Integrated Care Centre and the Trafford mobile screening van only), East Cheshire (Macclesfield District General Hospital and Stockport mobile breast screening van locations) and East Lancashire (Burnley General Hospital and East Lancashire mobile breast screening

van locations). Recruitment is over a 16-month period and sites will each be open to recruitment to BC-Predict for a period of 8 months.

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

Confidential Patient Information Requested

Cohort

The following inclusion criteria have been established for the various study phases:

Proof of Principle Study - Phase 1 inclusion criteria

- Attending for breast screening at relevant site.
- Mammogram to be performed at relevant site on day of consent to the study.
- Able to complete the BC-Predict risk assessment questionnaire at their screening visit.
- Willing to receive their breast cancer risk information.
- Born biologically female.
- Approximately 20 participants across three sites.

Proof of Principle Study - Phase 2 inclusion criteria

- Invited for breast screening at active site.
- Able to complete the BC-Predict risk assessment questionnaire
- Willing to receive breast cancer risk information.
- Born biologically female.
- Approximately 180-360 participants across three sites.

Main study inclusion criteria

- Born biologically female
- Invited for first breast screening with the Greater Manchester, East Cheshire, or East Lancashire breast screening programmes or invited for a mammogram at East Cheshire or East Lancashire and aged between 57 and 63 years.
- 8,000 who join the study, but 18,700 who are invited.
- Main study controls - approximately 18,700 but these women will not be recruited to the study.

Support is requested for three elements of the application activity. In Phase 1 of the proof of principle study, support under the Regulations is requested to enable the research assistant access to confidential patient information from the NHS Breast Screening Service (NBSS) system in order to invite patient to the study. Support is requested to allow the applicants remote access to confidential patient information held within the NBSS database at the three NHS Trusts in order to extract information in relation to relevant patients in order to invite them to participate in the study, together with the control cohorts.

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

- Name – to allow invitation and risk letters,
- NHS Number – validation and linkage,
- Date of birth – sample validation,
- Date of death – sample validation and analysis,
- Full Address and postcode – send invitation and risk letters,
- GP Name and address – to enable outcomes to be shared,
- Breast Screening number – to enable outcomes to be shared.

Confidentiality Advisory Group Advice

A Sub-Committee of the CAG considered the applicants written response to the request for further information in correspondence.

1. **Clarify the overall duration of support which is required under the Regulations for the project.**

The applicants confirmed that support was required up to May 2020, which will cover the study duration from first invitation through to the circulation of the final risk letter.

Members received the clarification and no further issues were raised.

2. **A wider communications strategy should be established in order to raise the profile of the project in the public domain. The purpose of this is to inform women eligible for breast screening who may be included in the control cohort about the project and provide an opportunity for these individuals to raise an objection to the use of their data. An overview of how and where information will be displayed should be provided, together with a copy of any information materials which will used to facilitate this. An explanation of how the dissenting mechanism would be operated should also be provided.**

A communications strategy was provided for the study, which was supported by a poster which would be utilised to raise the profile of the study. It was clarified that the communications strategy had been considered by members of the trial patient advisory group.

Members were assured by the planned communications strategy for the study and commended the involvement of the patient advisory group. It was noted that the supporting poster did not clearly explain that, for patients in the control group who were not invited to participate in the trial, researchers would have access to confidential patient information; however, this would not be retained for analysis. The CAG requested that the poster be revised to more accurately describe the access to patient identifiers within the study.

The applicants provided a revised poster which addressed this outstanding issue. The CAG received the document and no further issues were raised.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 09 July 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Manchester University NHS Foundation Trust, V14.1, 2017/18, confirmed satisfactory by NHS Digital email on 14 June 2018**).

Reviewers:

Name	Capacity
Ms Sophie Brannan	CAG Lay Member
Dr Patrick Coyle	Vice Chair
Professor Barry Evans	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Mrs Diana Robbins	CAG Lay Member
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **Avoiding Cardiac Toxicity in lung cancer patients treated with curative-intent radiotherapy to improve survival**
CAG reference: **18/CAG/0071**
IRAS project ID: **216324**
REC reference: **18/YH/0058**

Context

Purpose of Application

This application from Leeds Teaching Hospitals NHS Foundation Trust set out the purpose of medical research which aims to understand the link between the dose of radiotherapy treatment given treat patients with lung cancer and potential damage caused to surrounding organs, including the heart, which is caused by the radiation therapy. The proposed trial will use retrospectively collected radiotherapy data from the Leeds Teaching Hospitals NHS Foundation Trust and the Christie NHS Trust, in Manchester, to investigate this.

The overall project comprises of seven work packages, of which this application concerns work packages one and two. The hypothesis of this study is that by sparing radiation sensitive cardiac sub-structures, survival in lung cancer patients after radiotherapy can be improved by at least 10% at one year. The applicants explain that the two work packages included in this application are not designed to answer this question, but will contribute to a body of evidence linking radiation heart dose and survival of lung cancer patients.

Patients will be identified from electronic radiotherapy records held at each institution by members of the clinical care team. Confidential patient information will be disclosed to Public Health England in order to linkage with the National Cancer Registration and Analysis (NCRAS) dataset.

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 who received curative intent radiotherapy in the Leeds Teaching Hospitals NHS Foundation Trust and the Christie NHS Trust for lung cancer, between 01/01/2010 and 30/12/2016. There is a proposed sample of 2,050 patients.

The following items of confidential patient information will be used for the purposes described:

- NHS Number – linkage,
- Date of birth – linkage and analysis (used to calculate age at diagnosis),
- Sex – linkage,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

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

1. **Provide further information around the retention of the source database, from which the pseudonymised database to be used for analysis, would be created to confirm whether this data will be retained, for what duration and in what format and who will have access to this information.**

It was clarified that the source database consisted of clinical data and is held in the clinical systems of Leeds and Manchester and will remain within the clinical system. This is held in an electronic format within secure radiotherapy database systems in Leeds and Manchester. After the study, individual patient data will remain in the secure systems, only clinicians with a duty of care to the individual can access the data.

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

2. **Patient and Public Involvement and Engagement – further work should be undertaken in this area in order to explore the acceptability of using confidential patient without consent for the application purposes. An overview should be provided around the activity which has been carried together with feedback from those involved. If activity has not yet been carried out in this area, a detailed plan of work which is planned in this area should be provided for consideration. If the responses given from any patient interaction were negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.**

The applicants explained that the team in Manchester would present the Cardiac Toxicity Programme to Patient and Public Involvement and Engagement (PPIE) representatives at a Cancer Panel meeting in late July, which had been arranged through the Manchester Biomedical Research Centre Advanced Radiotherapy Team's PPIE team. The event would involve a short presentation by Dr Alan McWilliam around the study followed by a discussion on the use of identifiable data in the context of this project.

The team in Leeds had plans to discuss the project in the Radiotherapy Research Patient Public Involvement group. The meeting was expected to take place in late August with patient consultation on this matter soon afterwards.

The Sub-Committee received the response and it was agreed that an interim report on this findings would be required for consideration. Members were content to provide a recommendation of conditional support for the application on the basis that feedback from the planned patient and public involvement and engagement activity is provided within one month of the activities being undertaken.

3. **Patient Notifications and Dissent – a communications strategy should be established for the project, which also enables a meaningful dissenting mechanism for patients. Copies of any documentation should be provided for review by the CAG, together with an overview of how the dissenting mechanism will be maintained. It is recommended that assistance is sought from patients and members of the public to review any documentation, to ensure the information is accessible to wide audience and this should form part of the ongoing plans for PPI engagement.**

It was confirmed that information was already displayed on the website for the Christie NHS Trust website around the use of data in research, which was supplemented by posters in clinics. The website information provided patients with information around how to opt-out of this data usage.

It was also confirmed that information about the study would be available via the Yorkshire Cancer Research website.

Leeds Teaching Hospitals NHS Foundation Trust would be displaying information about the project on the Leeds radiotherapy project website and twitter page, which was publicly available and would provide a contact telephone number and email address to enable patients to withdraw from the study.

The Sub-Committee considered the response and it was noted that the information which was currently available via the Christie NHS Trust website appeared to the standard privacy policy and did not include any specific information about the study. The notification which was included in the Yorkshire Cancer Research website did not appear to be written for a public audience and was quite difficult to locate. It was further noted that information could not be located on the Leeds Radiotherapy project website. The applicants were asked to provide further response in this area to ensure the communications strategy was clear for the project.

The applicants provided a patient information leaflet, which included the email address and telephone number which would facilitate patient contact and enable study-specific objections to be raised. It was confirmed that this had been added to all of the previously referenced websites and links to the information were provided.

The Sub-Committee received the document and supporting links. Members were assured by the communications strategy for the project and no further issues were raised in this area.

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. An interim report on the findings from the planned patient and public involvement and engagement activities should be provided by the end of September 2018 for consideration. 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. Favourable opinion from a Research Ethics Committee (**Confirmed – 16 March 2018**).
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed – Public Health England (X25) satisfactory reviewed grade on Version 14.1, 2017/18).**

Reviewers:

Name	Capacity
Ms Sophie Brannan	CAG Lay Member
Dr Tony Calland MBE	Chair
Dr Rachel L Knowles	CAG Member
Mrs Diana Robbins	CAG Lay Member
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **What changes in Medium Secure Care? A long term follow up study of outcomes, care, supervision and patients' experiences.**

CAG reference: **18/CAG/0090**

IRAS project ID: **237697**

REC reference: **18/WA/0157**

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

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

1. **Confirmation should be provided of the legal basis under the common law duty of confidentiality to 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.**

The applicants confirmed that support under the Regulations was requested to extend to the activity of accessing and extracting confidential patient information and anonymous research data from healthcare records within the Medium Secure Unit.

It was explained that confidential patient information will be stored separately within a password-protected excel document only accessible by the Chief Investigator (Dr Ruth Bagshaw) and PhD student (Charlotte Hill). Anonymous data will also be stored in an encrypted, password protected excel document, also only accessible by the Chief Investigator and PhD student. Both excel documents will be stored in a password protected research folder on the shared drive in the ABMU secure network system.

The Sub-Committee received the response and were content to provide a recommendation of support under the Regulations to legitimise the access to and extraction of confidential patient information from records at the Medium Secure Unit.

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.**

It was confirmed that the study would not follow up patients who were discharged to prison from the Medium Secure Unit. It was clarified that patients discharged to less secure settings or the community would be followed:

- up to the point of re-admission to a forensic mental health service,
- up to the point of re-conviction, or
- up to six years post-discharge if they had not been re-admitted or re-convicted within this time period.

The applicant confirmed that for those who were re-convicted, the actual sentence for the conviction would not be known or whether the individual was imprisoned as a result of their crime.

It was confirmed that there was no requirement to access to prison records at any point. The applicant advised that they had liaised with Her Majesty's Prison and Probation Service (HMPPS) and the Ministry of Justice concerning the correct legal basis to access the forensic information necessary for the project, both confirmed this would be specific to the Ministry of Justice, and would not require HMPPS involvement.

Members received the clarification and no further issues were raised in this area.

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.**

It was confirmed that Local Collaborators are Consultant Clinical/Forensic Psychologists of the follow-up forensic mental health services where patients were discharged. These individuals would have had access to information regarding patient psychiatric and forensic history in order to carry out risk assessments and risk management of the patients.

The applicant explained that the participating Consultant Forensic/Clinical Psychologists had requested information about the project before agreeing to act as Local Collaborators. They were provided with the project proposal, which informed them that the project relates to individuals discharged from a medium secure unit. It was confirmed that the Local Collaborators were NHS employees and were HCPC registered psychologists working under confidentiality principles and a duty of care with both contracts. The Local Collaborator would require the NHS number in order to (1) locate follow up records and (2) identify the Responsible Clinician of those still in contact with services.

The clarifications were received by the Sub-Committee and no further issues were raised in this area.

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.**

It was confirmed that both hospital number and NHS number would be required as the hospital number was specific to Abertawe Bro Morgannwg University Health Board; however, NHS numbers would be used across all the Welsh Health Board's involved. The applicant provided the following further justification to support the requirement for both data items:

Hospital number: This is a specific number used by all services within one specific health board; in this case it will be the patients' hospital number for Abertawe Bro Morgannwg University Health Board. Records within the Medium Secure Unit will only have hospital number for most patients; few will also have the NHS number available from these records. The hospital number will be needed to locate follow up records of patients discharged to less secure settings and community services within this health board.

NHS number: In order to inform Local Collaborators of the relevant healthcare records necessary from their health board for the project, NHS number will be needed. Welsh PAS will be used, which is a system that will allow identification of the NHS number from the hospital number (access to Welsh PAS has been granted by the Caldicott Guardian on the condition of gaining appropriate ethical approval).

The Sub-Committee received the response and were assured that the requirement for both data items had been justified.

5. **Confirm when date of death will be deleted from the dataset.**

The applicant confirmed that year of death would be collected, if patient died whilst admitted at the Medium Secure Unit or within the six year follow up period, to confirm which patients could no longer be followed up. The year of death will be stored within the password-protected, patient identifiable excel document (with patient name, known aliases, date of birth etc.). Once the case note analysis had been completed year of death, along with other patient identifiable information would be destroyed immediately. This was anticipated to be completed by September 2019.

Members received the clarification and no further issues were raised.

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,**

It was confirmed that the Service User and Carer Participation Service (SUCPO) group is part of Hafal. The PhD student attended this group, as well as a separate carer group that are also part of Hafal. The SUCPO group did comprise of some individuals who had previously experienced medium secure care. Both groups were asked to share their thoughts on accessing healthcare records for the purpose of the project and encouraged to share any ideas about 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.**

It was explained that the Student Investigator had requested to attend community meetings at the Medium Secure Unit. Community meetings involve discussions of concerns, updates and ideas related to the service, and both staff and current patients attended. Each ward has an individual community meeting. The PhD student had attended two community meetings (9-12 patients in each group). Information about the project was shared, including the aim, method (case note analysis of patient records and interviews), and implications. The patients from both community meetings showed an interest and saw the benefits of the project. There was no aversion to the methodology used, and they provided ideas of factors of care to consider.

Given that the community meetings were in large groups, if current patients felt that they would prefer to speak to the Student Investigator on a one to one basis, or would rather share their thoughts through the ward manager, then they were provided guidance to speak with the ward manager, who would liaise with the student.

The Student Investigator had also attended the Service User Friendly Group, which is a voluntary group led by current patient representatives of the Medium Secure Unit (approximately fifteen patients present). The project was described together with the proposed methodology. Similar to the community meeting, the attendees supported the project and agreed that it was necessary. The group shared their thoughts of what was useful and unhelpful whilst in Medium Secure Care, which would help provide ideas of factors of care to focus on for the project. They also disclosed issues that arise following discharge from secure services, specifically the lack of support. The group felt that the research should look into factors associated with aftercare and the support available post-discharge to help highlight improvements.

The Sub-Committee received the response and were satisfied with the level of patient and public involvement and engagement activity which had been undertaken. No further issues were raised 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,**

The applicants submitted a revised general information leaflet which had been amended to include guidance around how individuals could dissent.

The document was received and no further issues were raised.

b. It is recommended that guidance is sought from patients and the public around the content of the document,

It was clarified that the amended version of the general information leaflet had been tested with current patients at the Medium Secure Unit. Those approached stated that the document was understandable, but suggested changing the title of the section 'Dissemination of findings', which was now referenced as 'where the findings will be reported'. The patients also confirmed that the objection mechanism was understandable and straightforward.

Members received the response and were assured by the patient comments around the document. No further issues were raised in this area.

c. Provide an overview of how the objection mechanism will be operated and respected for the study,

The amended general information leaflet outlined the mechanism of how individuals can object to their records being used in the project. Individuals were encouraged to contact the Chief Investigator of the project (contact details available on the document). The Chief Investigator will not ask any questions and will respect the individuals' decision and will immediately remove the individual's identifiable information from the patient identifiable excel document. The Unique Reference Number and the associated research data from the research excel document would also be removed.

The Sub-Committee was satisfied with the proposed dissenting mechanism and raised no further issues in this area.

d. Clarify whether patient records will be checked for evidence of historical dissent against use of data for purposes additional to direct care,

It was confirmed that the Student Investigator would check records for evidence of historical dissent – where found, the individual would be removed from the project dataset.

Members were satisfied with the response provided.

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,

It was explained that contact had been made with the communication's department, which were responsible for the contents displayed on Abertawe Bro Morgannwg University Health Board's website. The department advised that information about a research project had never been added to their website in the past. They stated that the only section that may be able to include information about the study was within the Research and Development section; however, it was unlikely for any member of the public to find the document through this section on the website.

It was confirmed that the Health and Care Research Wales website was the known resource for individuals/members of the public to be informed of research taking place across Wales. This site covered all research taking place across all the Welsh Health Boards. It is standard for any NHS research project approved by a Welsh NHS Research and Development department (R&D) to be able to submit their project to go on the Health and Social Care Research Portfolio. The portfolio provided information of each project taking place across the Welsh Health Boards and other Welsh projects.

The Student Investigator confirmed that she was currently liaising with Health and Care Research Wales to identify whether the portfolio was able to provide an outline of the mechanism for individuals to object for their records to be used for the project. The Student Investigator was currently developing an application to submit the project for inclusion on the portfolio. Projects were only approved once

complete REC approval had been granted. Along with this, the general information leaflets would also be available at the forensic mental health sites across each of the health boards involved in the project.

Members were assured that the alternative arrangements were appropriate for the project. Confirmation was required that the study information had been displayed on the Health and Care Research Wales website at the time of next annual review.

f. Confirm that the project complies with the Welsh Language Act 1993.

The applicant confirmed that the general information leaflets would be available in English and Welsh when displayed at the specific forensic mental health services.

The confirmation was received and no further issues were raised in this area.

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 study information was displayed on the Health and Care Research Wales website.
2. Favourable opinion from a Research Ethics Committee (**Confirmed – 12 July 2018**).
3. Security assurance arrangements (**Confirmed – NWIS SLSGA received 01 June 2018).**

Reviewers:

Name	Capacity
Dr Martin Andrew	CAG Member
Dr Tony Calland MBE	Chair
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **2018 NHS Adult Inpatient Survey**

CAG reference: **18/CAG/0098**

Context

Purpose of Application

This non-research application from Picker Institute Europe, CQC and NHS England set out the purpose of carrying out the 2017 NHS Adult Inpatient Survey, using standardised methodology to build up a national picture of patient experiences. A set of aggregated statistical data is produced which is shared with individual Trusts, CQC, NHS England and the Department of Health and used to monitor and compare the performance of Trusts, and to drive improvements.

This survey would be the 16th carried out to date. The methodology is well established and has been approved in principle by the CAG via Precedent Set Sub-Committee. The applicants confirmed that the survey methods are unchanged from the 2017 survey.

Participating trusts identify the sample in line with the inclusion/exclusion criteria, and disclose names and addresses to approved contractors for the purpose of mailing out the surveys (this data is held in a mailing file along with the unique identifying code which is printed on the survey itself). Demographic information for each potential participant is collected in a separate sample file, linked by the identifying code.

Picker Institute is commissioned to manage and coordinate the surveys under the title of the Patient Survey Coordination Centre, carrying out checks across the samples submitted by trusts and disseminating aggregated results (identifiable information is not received by the Patient Survey Coordination Centre).

As part of the drive to improve response rates (RR) and possibly reduce response bias, and to explore a move to a mixed mode methodology using online methods within the NPSP, a pilot study is being proposed across 10 Trusts, which would each be asked to provide an additional 1,014 patient, and provide mobile telephone numbers for them, *to test the effect of a three separate interventions in the 2018 NHS Inpatient Survey (IP18):*

- *Administering the questionnaire online (instead of a postal survey).*
- *Sending SMS reminders.*
- *Using a shorter questionnaire.*

The control arm of the pilot will be the main sample. This pilot is aimed at testing the effects of three different methods of invitation which combine postal letters and text messages, and the use of an online questionnaire. Inclusion of mobile phone numbers was approved for last year's survey via full CAG review – as the proposed pilot does not require the disclosure of any additional items of confidential

patient information, promotion to full CAG was not deemed appropriate at this stage. The interventions will be piloted as follows:

Intervention	Mailing 1 (M1)	Mailing 2 (M2)	Mailing 3 (M3)
Intervention 1	Postal letter with link to online questionnaire	Postal reminder with link to online questionnaire	Postal letter (no link) *and* hard copy of questionnaire
Intervention 2	Postal letter with link to online questionnaire, followed by SMS with link	Postal reminder with link to online questionnaire, followed by SMS with link	Postal letter (no link) *and* hard copy of questionnaire
Intervention 3	Same as main survey, with shorter questionnaire	Same as main survey	Same as main survey, with shorter questionnaire

It is noted that all pilot interventions will use the shorter version of the questionnaire.

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

Confidential Patient Information Requested

Cohort

- Inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in July 2018 (and earlier for smaller trusts), having had one overnight stay in hospital.

Exclusions:
- deceased patients,
- children or young persons aged under 16 years at the time of sampling,
- obstetrics/maternity service users, including spontaneous miscarriages,
- patients admitted for planned termination of pregnancy,
- psychiatry patients,
- day cases,
- private patients (non-NHS),
- any patients who are known to be current inpatients patients without a UK postal address,
- any patient known to have requested their details are not used for any purpose other than their clinical care, including those responding to posters displayed on hospital wards referring to the survey (the survey instructions request that all responses to posters are logged and used for this purpose).

The mailing file sent to contractors contains the following information:

- A standardised unique identifier code (see application for full details of how this is constructed)
- Title (Mr, Mrs, Ms, etc.)
- First name
- Surname
- Address Fields
- Postcode (where available)
- Mobile telephone number for those patients included in the pilot, from a total of up to 10 Trusts**.**

The sample data file (used to link demographic data to the survey responses, to aid analysis and to enable checks to be carried out for any errors in how the sample was drawn contains:

- The unique identifier code,
- Admission/discharge dates,
- Length of stay (this is calculated from the admission and discharge dates),
- Whether admission from Treatment Centre,
- Route of admission,
- NHS Site code on admission and discharge,
- Ethnicity,
- Gender,
- Year of birth,
- Indicator of recorded mobile telephone number (all patients not included in SMS pilots),
- CCG Code: to enable analysis at this level by stakeholders for the production of relevant indicators,
- ICD10 code.

The sample file is also shared with the Coordination Centre to enable centralised checks on the appropriateness of samples drawn. For clarity, please note that the Coordination Centre do **not** receive any names or addresses.

Confidentiality Advisory Group advice

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

1. **Confirm whether an assessment was undertaken in relation to the number of contacts proposed for the pilot interventions and the potential for this to have a negative privacy impact on potential respondents. Clarify whether this potential risk was discussed with the Inpatient Survey Advisory Group.**

It was explained that, for all pilot interventions, each contact with the patient would provide the option to opt-out from receiving any further contacts regarding the survey. The postal letters included a helpline to call and opt-out, the SMS messages also included this helpline as well as the online version of the survey. Similar to this year's proposed pilot interventions, other pilot studies within the NHS Patient Survey Programme have had a maximum of five contacts to patients and no issues were identified. It was clarified that no complaints were received during the 2017 pilot study that ran alongside the 2017 Inpatient Survey where patients received a maximum of five contacts (including SMS messages).

The applicant confirmed that the move to incorporating digital means of contacting patients had been consistently requested by Advisory Groups across the Survey Programme as a solely paper based approach was considered outdated, cost inefficient and contributed to response bias. The Advisory Group also discussed the increase in using SMS to issue appointment reminders from Trusts and the Friends and Family Test, demonstrating that now is the right time to pursue these alternatives. It is worth noting that the Patient Survey Programme as standard uses two reminders to patients, but already other national surveys such as the GP Patient Survey use four as standard. At the 2018 Inpatient Advisory Group the proposal to issue SMS reminders was discussed and approved.

In addition, the applicants explained that as evidenced in other projects, patients generally do not mind being contacted by SMS. It was noted that from the 2017 pilot study that ran alongside the 2017 Inpatient Study, no complaints were logged to be specifically due to receiving SMS messages. Within a current audit being undertaken by the applicants, it was explained that a survey was sent to patients asking about the use of mobile numbers and email addresses for CQC surveys. Patients were happy with the idea of using mobile data, saying: 'I would definitely be more likely to respond to a request for feedback via text or email. I would be happy for my information to be passed on' and 'I really like this idea, it's much easier and less time consuming'.

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

2. **Confirm whether the number of paradata items which will be collected have been tested to ensure that, in conjunction with survey responses, to ensure there is no potential that a patient could be inadvertently identified from the information. Clarify whether the paradata sample has been assessed to ensure that this does not contain any markers which may be considered identifiable in relation to the GDPR or the DPA 2018.**

It was confirmed that the pilot contractor was Quality Health. This organisation is currently the contractor for the pilot study running alongside the 2018 Community Mental Health Survey which also included the use of SMS and an online survey. It was explained that the fieldwork had now ended for this study and Quality Health had confirmed that in providing paradata from their SMS and online survey systems (the same systems they will be using for the Inpatient Survey Pilot Study), no identifiable information was available as part of the paradata dataset. Quality Health also confirmed that this would also be true for the Inpatient Survey Pilot Study and therefore, there was no risk of breaching GDPR/Data Protection Regulations. A detailed overview of the paradata items which would be provided by Quality Health to the Survey Coordination Centre for each participant in the survey was provided for information purposes.

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

3. **Provide details of the demographics and number of patients included within the Inpatient Survey Advisory Group.**

Details were provided in relation to the demographics of the three members of the Inpatient Advisory Group.

Members received the details and whilst no issues were raised which required further information, it was recommended that the applicants consider increasing the number of group members moving forward as it was commented that this was a limited sample.

4. **Clarify that Trusts would be advised in include both a telephone number and email address on the notification posters to facilitate opt-out.**

The applicant explained that a webinar was held for Trusts on Thursday 21st June 2018 and 108 individuals attended. The project lead explained that both a telephone number and email address (if available) must be included on the dissent posters. Following the webinar, a document summarising all Q&A along with the webinar slides was published on the NHS Surveys website and links were sent via email to Trust contacts.

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

5. **Clarify whether there are any plans to include private patients within any future Inpatient Surveys.**

The applicant confirmed that, as the present time, there were no plans to include private patients within any future iterations of the Adult Inpatient Survey. This was in line with the current purposes of the data collected by the national survey and the current regulatory needs of CQC.

The response was received and no further issues were raised in this area.

<u>Additional Amendments</u>

The applicants detailed two proposed amendments to the project methodology within the response letter as follows:

1. **Faster reminder Letter**

The applicants proposed reducing the time frame between the first, initial mailing and the second mailing (first reminder letter) from 10 days to five working days. This follows a methodological pilot undertaken alongside the 2017 iteration of the Adult Inpatient Survey. For this pilot, the impact of reducing the time gap between the first and second mailing on overall response rates was investigated. This pilot found that there was a significant increase in response rate of three percentage points when the time gap was reduced to five days between these mailings, compared to the advised 10 days (current methodological approach). This modification did not constitute a change to the information being provided by the Trust for the purpose of mailing nor does it introduce a change to the data flow of information or increase the number of contacts made with patients. This change will only result in a change to timings. As standard, Trusts will be required to conduct local checks for deceased patients prior to the second mailing (as is standard on the programme).

The Sub-Committee received notification of the change and no issues were raised.

2. Mobile Phone Number Indicator

It was referenced within the initial application that mobile phone indicator would be submitted for the control arm (i.e. their main 1250 sample) from Trusts involved in the 2018 pilot study. The applicants confirmed that this would be extended to cover the mainstage survey, i.e. this will be provided for all Trusts participating in the survey and not limited to just the pilot trusts. Trusts would be asked to provide this information in the same way as instructed for pilot Trusts, namely that only an indicator needs to be assigned to each patient to note they have a mobile phone number recorded, or they do not. The Trusts would not be providing mobile phone data for any of the patients in their mainstage samples. The applicant explained that this change would enable better understanding the availability and coverage of mobile telephone information held by NHS trusts on patient records.

The Sub-Committee received notification of the change and no issues 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, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital review of Version 14.1, 2017/18, Capita Business Services Ltd., Membership Engagement Services and Patient Perspectives by email 18 July 2018**).

Reviewers:

Name	Capacity
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **Investigating the use of 'frailty' on death certificates and admission information- a retrospective case note analysis**
CAG reference: **18/CAG/0085**
IRAS project ID: **243673**
REC reference: **18/NW/0399**

Context

Purpose of Application

This application from Sheffield Hallam University set out the purpose of medical research which is a preliminary study to investigate the use of the term 'frailty' and whether the use in case records is consistent with the use on death certificates. Frailty is a significant factor in the morbidity and mortality of older people. Frailty has been defined as "…a distinctive health state related to the ageing process in which multiple body systems gradually lose their in-built reserves" (BGS, 2014a) and is a recognised syndrome in the UK. Increasing numbers of older people are admitted to hospital with acute problems and are either admitted with frailty or become frail after admission. Frailty affects clinical outcomes and may be a cause of death but is not an inevitable consequence of ageing. This leads to questions of how frailty might be detected and prevented in an inpatient population.

The project will involve a retrospective case note review of patient records at Sheffield Teaching Hospitals NHS Foundation Trust. The Bereavement Services Manager will identify the patient cohort for inclusion from the hospital database of recorded deaths – this initial identification is out of scope for the CAG application, as the individual has legitimate access to this information. Patient names and hospital numbers will be used to request patient records in order to capture wider clinical information. Support is sought under the Regulations to support the disclosure of this information to the applicant and legitimise access to the patient cohort medical records in order to extract the pseudonymised dataset required for analysis.

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 who died within Sheffield Teaching Hospitals NHS Foundation Trust during the six month period between the beginning of January 2017 and the end of June 2017, who had the term frail/frailty or associated synonyms recorded on their death certificate. The sample size is estimated to include 301 patients.

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

- Name – validation and identification of cohort,
- Hospital number– validation and identification of cohort,
- Date of birth – to note age at event for analysis,

- Date of death – sample validation (ensure death occurred within study inclusion period),
- Postcode (District Level) – analysis,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advice Team advice

The Confidentiality Advice Team received the applicant's below response to the request for further information detailed within the provisionally supported outcome in correspondence.

1. **Confirm that information materials will be displayed on the Trust website in order to promote the research within the wider public arena.**

The applicant provided a link to the Sheffield Clinical Research and Innovation website, which was a partnership between Sheffield Teaching Hospitals NHS Foundation Trust and the University of Sheffield. The website provided information to patients and the public around research which was currently being undertaken. Details in relation to the study were available on the site for information purposes.

The information was received and no further issues were raised in this area.

2. **Confirm that, despite national policy in this area, the Trust does not operate a mechanism to record patients' dissent against the wider use of data for purposes in addition to direct care.**

The applicant confirmed that the query had been referred to the Legal Services Manager within the Patient and Healthcare Governance Department at the Trust for information. The response explained that whilst patients would not have specifically been asked whether they consented to the use of their data in research, during their contact assessment, patients do specifically have to provide consent for their data to be shared in relation to their care. If a patient had raised any specific objections, they would be recorded at this time as the assessment form enabled the patient to specify individuals with whom they did not want their data to be shared. The applicant confirmed that this completed assessment form was available on both the electronic records system and within the patient's paper record file – this would be checked for any evidence against the use of information for wider purposes prior to accessing the patient's record for the study.

The response was received and no further issues were raised in this area.

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. Favourable opinion from a Research Ethics Committee (**Confirmed – 11 June 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Sheffield Teaching Hospitals NHS Foundation Trust shows a satisfactory reviewed grade on V14.1, 2017/18**).

Reviewers:

Name	Capacity
Dr Tony Calland MBE	Chair
Dr Rachel L Knowles	CAG Member
Mr Andrew Melville	CAG Lay Member
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **Audit: evaluation of availability of patient contact details for use in the NHS Patient Survey Programme**

CAG reference: **18/CAG/0076**

Context

Purpose of Application

This application which was submitted by the Picker Institute, on behalf of the Care Quality Commission, sets out the purpose of audit which aim is to understand the availability and validity of digital contact information, including mobile telephone numbers and email addresses held by NHS organisations on their information systems (most likely PAS) in relation to patients. The audit is being undertaken as part of a wider assessment to understand whether it would be feasible to move data collection for the NHS Patient Survey Programme to a digital methodology.

The applicants will be requesting that all organisations which participate in the NHS Patient Survey Programme transfer confidential patient information in relation to their patients within a specific time period to the Coordination Centre, based at Picker Institute Europe, for analysis by Picker Staff. The analysis will enable the CQC to determine whether new methodologies can be employed to facilitate the gathering of patient feedback.

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

Confidential Patient Information Requested

Cohort

This audit involves the retrospective sample of all patients, regardless of what contact information is held, as follows:

- Trusts will be asked to sample all patients who were discharged during October 2018 (for the adult inpatient survey),
- Community mental health services would be asked to sample all service users in contact with the service in May 2018,
- Specialist children's trusts, we would ask for all children discharged during October 2018,
- There will be a maximum of 2,000 patient per Trust included within the audit.

The following individuals would be excluded from the audit sample:

- Patients under the age of 16 years old (for the adult inpatient, emergency department and maternity populations only),
- Service users under the age of 18 years old (for the community mental health population only),
- Parents of children and young people for children inpatient and day-case services,
- Patients and service users who were not accessing an NHS based service (ie: include private patients),
- Patients who had specifically indicated that their use of contact details should be for nothing other than their clinical care.

The following items of confidential patient information will be provided for analysis to be undertaken:

- Unique identifier/ record number: this would be assigned when the sample is compiled,
- Year of birth,
- Gender,
- Ethnicity,
- Telephone number (mobile number only),
- Email address,
- Flag to indicate whether telephone number is for the patient,
- Flag to indicate whether email address is for the patient,
- Date contact information collected (for both contact details separately),
- Date of validation (if applicable) (for both contact details separately),
- Whether consent given for contact information to be used (for both contact details separately).

Confidentiality Advisory Group advice

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

1. Clarify the inclusion criteria in relation to child patients and their parents within the audit.

It was confirmed that parents of children young people would be included as the anecdotal feedback the applicant's had received from some consultation work with Trusts had indicated that the contact telephone number on Trust records for this population would relate to the parent, carer or guardian rather than the patient themselves given the age of the cohort. For Trusts who have children and young people services, Great Ormond Street as an example, the case data (ie: the patient selected) would be the child/ young person, as that's the information their records hold, but the associated telephone number or email address is most likely going to relate to the parent.

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

2. The acceptability of using confidential patient information for the application purposes should be tested with an appropriate patient and public group. Feedback from this activity should be provided ahead of any recommendation of support coming into effect.

The applicant explained that engagement with patients and the public was sought via two approaches: the first through CQC's online community and the second by approaching individual NHS Trust patient engagement groups.

The CQC online community is a group of members of the public, many of whom have first-hand patient experience, who have volunteered to provide feedback to CQC on an ad-hoc basis. Requests for feedback are sent once a month and run for two weeks.

In order to gather informed feedback from the online community, background information on the NHS Patient Survey Programme and the planned audit activity was provided upfront. A copy of the information is provided as an appendix within this letter.

Members were asked to answer the following questions, with 83 responses received in total.

Do you support CQC's use of confidential patient information without consent for the proposed audit activity?

- Yes – 70% (58)
- Maybe – 12% (10)
- No – 18% (15)

Do you have any concerns about CQC's use of confidential patient information without consent for the proposed audit activity?

- No – 64% (53)
- Maybe – 12% (10)
- Yes – 24% (20)

It was recognised that the majority of respondents stated they would support CQC using confidential patient identifiable information without consent for the planned audit activity. The minority of respondents, who answered 'no', were asked a follow up question, to understand the reasons behind their objection. The reasons given were (1) fears over data security and potential breaches or the sharing of data with third parties and (2) a general objection to any data being shared without consent. Reassurances can be given to patients and members of the public following the introduction of GDPR and the strict regulations around the use of personal data.

Regarding concerns over data security and potential breaches, the process in place for the transfer of data is a tried and tested method between the Survey Coordination Centre and NHS Trusts as standard on the survey programme. All data is transferred to the Coordination Centre via a secure File Transfer Portal (FTP). Each NHS Trust has their own folder on the FTP with secure log in and password details. The folders are not accessible to anyone outside of the Trust. The access information adheres to guidelines within the GDPR around format of passwords and is only communicated verbally: it is not emailed to anyone at a Trust. This ensures that emails are not sent to the wrong individual with login information included. The only patient identifiable information transferred as part of the audit will be mobile telephone number and email address. There will be no additional patient identifiable data transferred. Where breaches have occurred previously on the programme, this has been due to the inadvertent transfer of patient identifiable data to the Survey Coordination Centre, which the applicants did not have approval to receive. The applicants explained that they would be engaging with Trusts in advance of the proposed data collection exercise and releasing specific sampling instructions to enable Trusts to raise any queries or clarifications prior to the extraction of data. The importance of following the guidance will be strongly re-iterated to participating trusts to ensure that are no breaches in the prescribed data transfer processes. There have been no other breaches of the actual transfer process in place. The data shared as part of this audit will not be shared outside of the Survey Coordination Centre.

The majority of respondents (64%) stated that they did not have any concerns about the planned use of confidential patient identifiable information without consent for the audit. The minority of respondents, who answered 'yes', were asked a follow up question, to understand how CQC could address these concerns. The main themes within the responses were: (1) reassurances around the secure storage of data and (2) confirmation of when the data would be destroyed would be key to addressing these concerns.

The following quotes are verbatim examples of the concerns raised:

"Ensure that systems used are encrypted and appropriate security measures are used"

"That the information could get into the wrong hands or not be destroyed… after the process"

"Reassure patients about how they will store the data, how it will be used and what it means for patients."

Regarding the storage of patient identifiable data, the sample data submitted by NHS Trusts will be securely stored on an encrypted, external hard drive. This hard drive will remain at Picker (where the Survey Coordination Centre is based), in a locked safe. It will not be accessible to any third party or anyone outside of the Coordination Centre. When a file has been transferred from an NHS Trust to the FTP, the file will be immediately removed and stored to the external hard drive. No copies of the data file will be made or stored on any internal networks, or personal computer drives. No data will be emailed. When the analysis of the data has been undertaken, the data will be destroyed by the using a shredding software.

The applicants explained that they had also reached out to a five different NHS Trusts within the acute sector and asked for assistance with gathering feedback from their existing patient representative groups. Due to timescales of when the patient engagement groups meet, and some resourcing issues at the Trusts, they were unable to receive any feedback.

The Sub-Committee received the response and it was recognised that the majority within the patient and public engagement activity were supportive of the project. The applicants had provided information to address the specific concerns which were raised by those who were not supportive. Members raised no further concerns in this area and were content to provide a recommendation of support to the application.

3. **The patient notification poster should be revised to provide a clearer explanation of what the audit involves, what patient data will be shared and what the inclusion cohort is intended to be. A revised draft should be provided for consideration.**

The dissent poster was amended to clarify the purpose of the audit, what data will be involved and how to indicate dissent. A revised document was submitted for information.

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

4. **Provide confirmation that, for patients who have not provided consent for contact information to be used, their contact details would not be disclosed by the Trust.**

The applicant's confirmed that if a patient has not given consent for their contact information to be used for any other reason than for their clinical care, their details would not be disclosed by the NHS Trust.

Members received the clarification and no further issues were raised.

As part of the received response the applicants advised that the sampling month for the audit data collection had been changed to October 2018 to ensure that there is sufficient time to enable the participating Trusts to display the patient notification materials in advance of the data collection.

The Sub-Committee received the clarification and acknowledged the amended sampling month.

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

Specific Conditions of Support (Final)

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Picker Institute Europe shows a satisfactory reviewed grade on Version 14.1, 2017/18**).

Reviewers:

Name	Capacity
Ms Sophie Brannan	CAG Lay Member
Dr Patrick Coyle	Vice Chair
Professor Barry Evans	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Mrs Diana Robbins	CAG Lay Member
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **United Kingdom Childhood Cancer Study**
CAG reference: **18/CAG/0066**
IRAS project ID: **203822**
REC reference: **18/YH/0135**

Context

Purpose of Application

This application from the University of York set out the purpose of medical research to undertake follow-up of patients who were previously enrolled in the UK Childhood Cancer Study (UKCCS), which recruited childhood cancer patients and matched controls between 1991 and 1996. The UKCCS was established with the primary aim of investigating the potential causes of cancer diagnosed before 15 years of age, in England, Scotland and Wales.

The UKCCS has a case-control design: each child diagnosed with cancer (n=4430) during the study period (1991-1996) was matched on sex, date of birth (month and year), and area of residence (Family Health Service Authority in England & Wales, and Health Board in Scotland) to two children of the same age who did not have cancer.

The proposed study aims to continue the longitudinal follow-up of the established cohorts via linkage with hospital episode statistics, cancer registrations and mortality information, to be undertaken by both NHS Digital and NWIS.

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

Confidential Patient Information Requested

Cohort

English and Welsh patients previously enrolled within the UK Childhood Cancer Study (UKCCS). The cohort comprised of 4,430 cases of childhood cancer and 9,758 matched controls. It is estimated that 3934 cases and 8641 controls were resident in England and Wales.

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

- NHS number (Old-Style only) – linkage,
- Date of birth – linkage/validation and analysis,
- Gender – linkage/validation and analysis.

- Date of death – analysis,
- Cause of death – analysis,
- Ethnicity – analysis.

Wider clinical information will also be returned following the data linkage for analysis, including cancer site, type and behaviour and date of diagnosis.

Confidentiality Advisory Group Advice

1. **Clarify whether cancer registration information will be obtained via linkage with the National Cancer Registration and Analysis Service (NCRAS) maintained by Public Health England. If so, confirm that PHE have provided agreement in principle to the linkage via old-style NHS number and provide a revised data flow chart to include this data flow.**

It was confirmed that in England, cancer registration data would be obtained via NHS Digital; NCRAS would not be approached.

The clarification was received and no further issues were raised in this area.

2. **Clarify what involvement NHS England has in the project.**

It was clarified that there was an error in the original data flow diagram and the reference should have read the English NHS not NHS England. The applicant revised the data flow diagram to correct this and also provided clearer information in relation to the Scottish elements.

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

3. **Provide confirmation that the items of confidential patient information held will be retained in order to futureproof the project in order to facilitate linkage with wider NHS datasets.**

The applicant confirmed that the data required for linkage (pre-1996 NHS numbers) would be retained.

The response was received and no further issues were raised.

4. **Patient Notifications and Dissent – further work is required in this area to address the following points:**
    a. **A project-specific dissenting mechanism should be established – an overview should be provided around how the objection mechanism would work to ensure than any patient dissent is respected,**

The applicant explained that they had discussed the possibility of instituting a project-specific dissenting mechanism with NHS Digital, whereby individuals could opt out of this study whilst remaining in other secondary use investigations. It was confirmed, however, there was no procedure in place to facilitate this; NHS Digital cannot be contacted directly by individuals asking to: 1) be removed from a specific study should they be in it; or 2) forward linkage information (in this case UKCCS serial number) through to researchers so that data can be removed from the research database.

In order to understand the context of the information provided, a copy of the correspondence undertaken with NHS Digital was requested. A response was received from Louise Dunn, NHS Digital DARS Team, on 11 July 2018 which confirmed the information provided in the applicant's response. The clarification was received and the Sub-Committee was content that, in the circumstances of this proposal, a project-specific objection mechanism could not be operated by the applicant, due to the limited data items retained, or by NHS Digital on behalf of the project.

b. The draft website text should be revised to ensure this is accessible to a wide patient audience, includes a clear overview of the full project and includes details of how a patient can raise an objection to the use of their data within the project.

The applicant explained that, as a matter of routine practice, information about existing studies was only provided to patients and the public after close scrutiny by the research team, clinicians, and members of the existing Patient and Public Involvement (PPI) groups. It was further explained that, due to the requirement to have the necessary regulatory approvals in place before this work could be undertaken, the documentation which was previously submitted had been drafted as a very preliminary example, and had not been assessed by any external individuals.

The applicant confirmed it was always intended to construct the UKCCS information pages as part of the study's PPI strategy, and to ensure that these were considered fit for purpose by all stakeholders before being used. As suggested by the CAG, the applicant confirmed that they would also explore and develop a communication strategy as part of the patient and public involvement and engagement approach. It was confirmed that as a first step, the applicant had begun to revise the previously drafted text. It was confirmed that when all necessary approvals were in place for the project, patient and public consultations would be arranged to further develop and finalise the pages. The applicant confirmed that copies of all revised material, together with full feedback, would be provided at the annual review in 2019.

The response was received and no further queries were raised in this area.

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. Support extends to England and Wales only.
2. Support is extended to the complete cohort of patients and controls recruited to the UKCCS within England and Wales.
3. Patient and Public Involvement and Engagement activity – work in this area should proceed as per the overview provided within the application.
    a. An overview the activity undertaken together with any feedback from patients should be provided at the time of annual review,
    b. The patient notification materials and communications strategy should be discussed as part of this work to see if further improvements can be made and revised documentation provided for consideration,
    c. The dissemination of research findings should be discussed in order to improve the mechanism to share results,
    d. If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.
4. Favourable opinion from a Research Ethics Committee **(Confirmed – 27 April 2018)**.
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed – University of York, Department of Health Sciences Version 14.1, 2017/18, confirmed satisfactory by NHS Digital email on 13/06/18 and NHS Digital).**
6. Confirmation from the Head of Information Governance at NHS Wales Informatics Services of suitable security arrangements in respect of Welsh data processing via Caldicott Principles into Practice Assurance Report **(Confirmed – 23 July 2018)**.

Reviewers:

Name	Capacity
Dr Lorna Fraser	CAG Member
Mr Anthony Kane	CAG Lay Member
Dr Rachel L Knowles	CAG Member
Dr Murat Soncul	Alternate Vice-Chair
Ms. Kathryn Murray	Senior Confidentiality Advisor

Application title: **Household transmission of Cryptosporidium in NW England and Wales, 2018-19: Risk factors and likely mechanisms for secondary spread.**

CAG reference: **18/CAG/0084**

IRAS project ID: **227587**

REC reference: **18/SC/0201**

Context

Purpose of Application

This application from the University of Liverpool set out the purpose of medical research which aims to estimate the secondary spread of Cryptosporidium, which is a major contributor to human diarrhoeal illness and infection with this parasite causing over 4,000 cases of diagnosed illness in England and Wales each year, that happens in the home and identify asymptomatic infection, which might have a role in transmitting disease. In addition, risk factors and characteristics associated with secondary spread will be described, including any differences in transmission between species.

The study will identify 400 cases from NW England and Wales over the course of 2018-19, and invite them and their household to take part. Each case will complete a questionnaire and each household member will provide a stool sample. Data will be analysed to show factors associated with spread and stool samples will be genetically characterised to accurately describe patterns of transmission.

Cryptosporidium is laboratory reportable when confirmed, and cases can only be identified via surveillance. In order to identify patients/households to be invited to participate in the study, surveillance databases will be trawled by staff based at Public Health England and Public Health Wales. Staff will not have access to any wider information that they would do as part of their standard role; however, as the data will be used for a wider purpose (research), support under the Regulations is required to support this change in purpose.

For invited potential participants who do not raise an objection to the use of their data within the two weeks from invitation, confidential patient information will be passed from PHE/PHW to research nurses based at the NIHR Clinical Research Network North West Coast, in order to facilitate the invitation/recruitment process. The applying research team will not have access to any confidential patient information until consent has been provided by the patient.

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

Confidential Patient Information Requested

Cohort

- The study population is residents of North West England and Wales, 2018-19.
- Any laboratory confirmed case of Cryptosporidium isolated from one of the laboratories in NW England or Wales is eligible for initial inclusion as an index case.
- Study data will be collected for one year.
- The applicants are aiming to collect 400 index cases and their households with an approximate overall sample size of 1,000.

The following items of confidential patient information are required to facilitate the invitation process:

- Name,
- Full address and postcode,
- Date of birth – required to enable correspondence to be appropriately addressed to patient or parent/guardian,
- Telephone number – to facilitate the recruitment contact.

Confidentiality Advisory Group Advice

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

1. **Confirm that patients would be informed of the Cryptosporidium diagnosis prior to receiving the research invitation.**

The applicant explained that, following a positive test result, the local testing laboratory would send a report to the patient's GP who would inform the patient of their diagnosis. It was advised that was very likely that by the time the information reaches the surveillance system(s), the patient would have been informed of their diagnosis. The applicant explained that a test sample of time from diagnosis to entry into the surveillance system had been undertaken which indicated an average period of 11 days. It was explained that the applicant was unable to confirm this in every instance as these processes were locally followed in each Trust. It was explained; however, the participants were provided with health advice and information on cryptosporidiosis and encouraged to discuss the study freely with their GP if they wished.

The Sub-Committee was assured by the response provided. It was commented that, whilst it was considered unlikely that patients would receive the study invitation prior to receiving their diagnosis, it would be helpful if details were provided in the invitation letter, in case this situation should arise. Members recommended that patients were provided with details of who to contact in this circumstance, either their GP or the clinician who took their sample. The Group agreed that this revision to the invitation letter would be requested as a condition of support, to be reported back within three months of the date of this letter.

2. **Confirm whether date of birth could be translated into age prior to the release of data to the CRN, in order to reduce the identifiability of the disclosed dataset. If full data of birth is required, stronger justification is required to support this.**

The applicant confirmed that date of birth would be translated into age, prior to the release of data to the CRN and the protocol would be updated to include this revision.

The response was received and no further issues were raised in this area.

3. **Clarify the overall duration of support under the Regulations which is required to facilitate the recruitment process.**

The applicant confirmed that support under the Regulations was required for a period of one year (from the first case accessed) plus 28 days (to fully recruit the last case).

The clarification was received and no further issues were raised in this area.

4. **Confirm whether the CRN staff, when contacting potential participants by telephone around the project, will leave a voicemail in connection with the study.**

The applicant confirmed, as stated in the protocol, that voicemails would not be left when attempting to contact patients by telephone. It was confirmed that, following three unsuccessful attempts, the potential participant would be removed from the line list and no further attempts to contact would be made.

The response was received and no further issues were raised in this area.

5. **Patient and Public Involvement and Engagement – work should be undertaken in this area in order to test the acceptability of using confidential patient information without consent for the project aims. It is also recommended that advice is sought from this engagement activity around what additional information could be displayed via a webpage to supplement the invitation materials. An overview of the activity undertaken in this area should be provided, together with feedback from the patient and public representatives. If the responses given are negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.**

The applicant confirmed that they had taken advice from the NIHR in this area and provided a supplementary document which outlined the justification for the approach to recruitment together with an overview of the ongoing patient and public involvement activities.

The document was received by the Sub-Committee and no further issues were raised in this area.

6. **A wider communications strategy should be developed to raise the profile of the study – it is suggested that this could link with the information which is already published online by PHE about Cryptosporidium. Feedback should be provided around what additional communications will be put in place, together with a draft of any information for consideration.**

The applicant confirmed that they had agreed website content with Public Health Wales (PHW), which will host the study webpage once all necessary approvals were in place. A copy of the text was provided for information purposes and it was explained that this was derived from a similar study which had been carried out by PHW. The information would also be made available in the Welsh language via the website. The applicant also confirmed that information would be displayed on the Health Protection Research Unit (funded in part by the NIHR) webpage once approvals were in place for the project.

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

7. **The invitation letter should be revised to include alternative contact details to facilitate patient objection. A link should also be included within the document to the webpage details referenced at point six above, to provide further information.**

The applicant confirmed that this point had been actioned and a revised document was provided for review. It was clarified that patients would be able to opt-out via contact with a freepost address, a landline telephone number or specific manned email address at Public Health England and Public Health Wales.

The revised document and clarifications were received by Members and no further issues were raised in this area.

8. Confirm which organisations will be processing confidential patient information with support under the Regulations to enable the IG Assurance to be checked.

The applicants provided confirmation that support would be extended to Public Health England, Public Health Wales and the Clinical Research Network NWC which was hosted by the Royal Liverpool and Broadgreen University Hospitals NHS Trust. NHS Wales Informatics Service had provided confirmation of security assurance direct to the CAG. NHS Digital provided security assurance via the satisfactory reviewed grade of the IG Toolkit submission for the two remaining organisations.

The response was received and no further issues were raised in this area.

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. The invitation letter for the project should be revised to include detail of who a patient can contact in the event that they have received the study invitation prior to receiving confirmation of their Cryptosporidium diagnosis. The revised document should be provided within three months of receipt of this letter.
2. Favourable opinion from a Research Ethics Committee (**Confirmed – 20 July 2018**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission for organisations processing data in England and NHS Wales Informatics Service CPIP Assurance for organisations processing in Wales (**Confirmed – SLSGA from NWIS dated 31/05/2018, NHS England, V14.1, 2017/18 IG Toolkit reviewed satisfactory grade confirmed via website, Royal Liverpool and Broadgreen University Hospitals NHS Trust, V14.1, 2017/18 IG Toolkit reviewed satisfactory grade confirmed via email dated 06 July 2018**).