Health Research Authority

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

August 2019

New applications

Name	Notes
Ms Clare Sanderson	Alternate Vice-Chair
Ms Sophie Brannan	CAG Lay Member
Dr Liliane Field	CAG Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title

Telephone triage of critical illness using NHS Pathways

CAG reference

19/CAG/0043

REC reference

19/YH/0076

Appendix 1. Confidentiality Advisory Group Sub Committee Minutes

IRAS Project ID

255767

Context

Purpose of application

This application from the University of Sheffield set out the purpose of medical research which aims to investigate whether NHS Pathways, the decision support system from NHS Digital used for telephone triage by NHS 111 and five 999 Ambulance Trusts in England introduced in 2018, can identify cases of potential critical illness with enough sensitivity and specificity, measured by equivalence with the National Early Warning Score 2 (NEWS2) acuity. This will help to understand if the new triage algorithms can identify persons at risk of clinical deterioration from an illness and in need of emergency care without over-triage to the finite resources of the emergency ambulance service.

The study will use a retrospective patient cohort who was triaged using the new algorithms following a 111 or 999 call received by the North East Ambulance Service NHS Foundation Trust and treated at James Cook University Hospital. The study will compare NHS Pathways triage to an ambulance response against the initial NEWS2 recorded by the attending NEAS clinician and to non-ambulance care disposition against any subsequent attendance or admission at James Cook University Hospital within 12 hours of the first 111/999 call and the initial NEWS recorded by the hospital.

Support is requested to allow the processing of confidential patient information by a Senior Information Analyst at North East Ambulance Service in order to identify the eligible patient cohort to be included in the study. North East Ambulance Service will link information for patients who received an ambulance to the electronic patient care records in order to extract relevant clinical information for analysis. This linked dataset will be anonymised by NEAS prior to disclosure to the applicant.

Support is also requested to allow the disclosure of specified items of confidential patient information from NEAS to James Cook University Hospital in order to facilitate linkage with wider clinical information required for analysis for the sub-

cohort of patients who received non-emergency triage disposition. An anonymised dataset would then be disclosed to the applicant 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 aged 16 or over, residing at a postcode covered by the South Tees CCG, who were triaged by a non-clinical 111/999 call handler using one of 24 pre-defined NHS Pathways illness symptom groups to receive either emergency ambulance or non-ambulance care. Patient sample is estimated at 7,400 patients. The planned period of retrospective data collection is a six-month period, between 01/01/2019 and 30/06/2019.

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

- Surname – sample validation and linkage
- NHS number – sample validation and linkage
- Date of birth – sample validation and linkage
- Postcode (Unit Level) – sample validation and linkage
- Sex – analysis

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence. An amendment request was also received for consideration alongside the provisional response.

1. **Provide assurance that sufficient time has been built into the linkage process to allow for data accuracy checks to be undertaken prior to the destruction of confidential patient information.**

The applicant explained that the North East Ambulance Service had advised that the data extraction and linkage process will take up to four working days to complete. Following which, the confidential patient information will be retained for a maximum of 10 additional working days to ensure that the South Tees Hospital NHS Trust and subsequently the applicant can confirm that the data for both patient cohorts in suitable for purpose.

Prior to the data processing and linkage phase of this project, the student applicant will meet with the analysts to ensure that the requirements of the study protocol are fully understood. It was explained that this would provide an opportunity to address any unforeseen queries to enable accurate data extraction.

The applicant further explained that the South Tees Hospital NHS Trust would undertake a cross-check of the linkage purpose to ensure confidence in the process and to avoid the requirement to re-run the request. Following which, the student applicant would receive the pseudonymised data set required for analysis.

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

2. **Confirm that at least four weeks lead in time will be allowed for patient objections to be raised.**

The applicant confirmed that the lead-in time for patient dissent would be extended to four weeks as requested.

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

Supplementary Detail

The applicant had queried whether it would be feasible to reduce the patient notification mechanism to remove the requirement to display on the South Tees Hospital Trust website. The applicant explained that due to the wider presence and promotion of the study via the various associated social media accounts, it was felt that this would attract greater online attention than publicising via the hospital Trust website.

Members considered the rationale provided by the applicant and agreed that the communications plans seemed robust. It was agreed information on the South Tees Hospital Trust no longer required publication.

Amendment Request

The applicant submitted an amendment request for consideration alongside the provisional response whilst confirmation of the security assurances remained pending. The amendment sought to change the retrospective recruitment period to 01 January 2019 to 30 June 2019, from the previous dates cited. The applicant also sought a change to the methodology to enable collection of patients NEWS2 score as the primary outcome of interest. It was explained that this scoring system has replaced the NEWS score which was described in the initial application. Both changes to methodology were proposed to make the study data collection and analysis more reflective of current practices.

The Chair agreed that the amendments appeared reasonable and did not alter the scope of support previously recommended but brought the focus of the study to a more contemporaneous period.

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 21 March 2019)
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit (DSPT) submission (Confirmed):

- North East Ambulance Service NHS Foundation Trust – Standards not fully met (plan agreed) NHS Digital provided assurance for the purposes of the CAG application, NHS Digital email 02/08/2019.

- Applicant to ensure that all staff processing confidential patient information for the purposes of this application activity have undertaken the mandatory Information Governance training prior to commencing processing.

    - South Tees Hospital NHS Trust – confirmed Standards Met achieved by NHS Digital email 20/06/2019.

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Name	Notes
Ms Clare Sanderson	Alternate Vice-Chair
Ms Sophie Brannan	CAG Lay Member
Dr Liliane Field	CAG Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title

2019 NHS Adult Inpatient Survey

CAG reference

19/CAG/0097

Context

Purpose of application

This non-research application from the Care Quality Commission set out the purpose of conducting the 2019 NHS Adult Inpatient Survey, using standardised methodology to build up a national picture of patient experiences. The outputs of this survey will be a set of aggregate statistical data that does not contain patient identifiable information.

This statistical dataset is used for a wide variety of purposes to support ongoing improvement in overall patient experience. The survey data will be used extensively by NHS trusts and Clinical Commissioning Groups (CCGs) in local improvement. The CQC will use data as part of its regulatory activities, as well as any other relevant functions. Individual level data for respondents will be shared with NHS England and the Department of Health and Social Care, containing sample file information. Individual level data for respondents and non-responders will be shared with NHS England to understand patients' experiences of NHS services and to drive improvements to them. The Department of Health and NHS England may use the results to generate aggregate indicators at local, regional and national level. These indicators form part of the range of Outcome Frameworks and other publications.

The data will also be shared with the Health and Social Care Information Centre, or other organisations, working on behalf of Department of Health or NHS England for the purpose of generating these indicators. NHS Improvement will use the trust level results (scored data) to inform their oversight model for NHS Trusts.

The 2019 Inpatient survey will be the sixteenth carried out to date. All trusts will draw a sample of patients according to set criteria and follow standardised materials and procedures for all stages of the survey. The methods for the 2019 survey are unchanged from the 2018 survey. The methodology is well-established and has been supported by CAG in previous years.

When administering the survey, NHS trusts will be advised to employ the service of one of four approved contractors to reduce the cost, burden and risk in the provision of survey data. In doing so, it is expected that the risks to data quality and delay to the timetable are reduced dramatically, as evidenced throughout the application. Some NHS trusts may opt to undertake the mailing of questionnaires themselves, avoiding the need to employ an approved survey contractor.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in July 2019 (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).
Data sources	148 acute and specialist NHS trusts
Identifiers required for linkage purposes	The mailing data is used to address questionnaires to the appropriate person. It contains: • Trust code. • A standardised unique identifier code, to be constructed as survey identifier, trust code followed by a whole number (consecutive across the sample of 1,250 patients from each trust), • Title (Mr, Mrs, Ms, etc.) • First name • Surname • Address Fields • Postcode (where available)

Identifiers required for analysis purposes	The sample data file is 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. This file contains: • The unique identifier code (as above) • 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 • CCG Code: to enable analysis at this level by stakeholders for the production of relevant indicators • ICD-11 code

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Secretary of State for Health and Social Care that the activity be fully supported.

Specific conditions of support (Final)

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. DSPT required for:

- Picker Institute Europe – confirmed by NHS Digital email on 17 July 2019
- Quality Health – confirmed by NHS Digital email on 24 July 2019

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- Patient Perspective – confirmed by NHS Digital email on 30 July 2019.

Appendix 1. Confidentiality Advisory Group Sub Committee Minutes

Name	Notes
Dr Tony Calland MBE	Chair
Ms Sophie Brannan	CAG Lay Member
Mr Myer Glickman	CAG Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title

Updating cancer survival index trends for England and Wales to 2016

CAG reference

19/CAG/0035

IRAS Project ID

259898

REC reference

19/LO/0426

Context

Purpose of application

This application from the London School of Hygiene and Tropical Medicine set out medical research which aims to update trends in the index of survival from all cancers combined in England and Wales, up to 10 years after diagnosis. The purpose is to assess progress in survival up to 10 years after cancer diagnosis, for all cancers combined, since the index was last published for patients who had been diagnosed up to 2010, as part of Cancer Research UK's (CRUK) research strategy launch in 2014. CRUK has set a target of improving 10 year survival in England and Wales for all cancer combined to 75% by 2030.

The proposed study will be an update of previous research which has been carried out by the same research team and will update the index of cancer survival for patients who received a first primary cancer diagnosis from 1971 to 2016. Information relating to patients in England would be provided by the National Cancer Registration and Analysis Service (NCRAS) at Public Health England. Information relating to patients in Wales would be provided by Welsh Cancer Intelligence and Surveillance Unit (WCISU). Confidential patient information will be transferred to the London School of Hygiene and Tropical Medicine for analysis.

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

Confidential patient information requested

Cohort

All adult patients aged 15 – 99 years, who were diagnosed with a first, primary invasive cancer from 1971 to 2016. The study involves a complete population-based set of cancer patient data which is expected to include over 10 million patients.

The following items of confidential patient information are required for the purposes of sample validation and analysis:

- Date of birth
- Date of death
- Date of cancer diagnosis
- Sex

Confidentiality Advisory Group Advice

1. Further information is required to understand the proposed exit strategy from the requirement for support under the Regulations:

a. Clarify how long confidential patient information would be retained and provide a justification for this.

b. Confirm the intended exit strategy from support under the Regulations.

The applicant that the Group adhered to the International Committee of Medical Journal Editors' recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, which included the statement that "investigators have a duty to maintain the primary data and analytic procedures underpinning the published results for at least 10 years. The ICMJE encourages the preservation of these data in a data repository to ensure their longer-term availability."

These policies are designed to enable re-analysis of the data in the event of criticism or allegation of fraud. This is particularly important: the Group's is a health domain that has frequently been controversial, and it is critical to retain public trust in the reliability of our results.

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

2. Provide an overview of the demographics of the Patient Advisory Panel.

The applicant explained that there appeared to have been a misunderstanding of information provided in the CAG application form. It was confirmed that the Advisory Panel included cancer survivors, but it was not comprised solely of cancer survivors. The applicant provided reference to the information included in the initial application form and confirmed that the Advisory Panel had subsequently been informed.

Further specific information was provided around two key patient panel members which had been involved with the Group's work.

The Sub-Committee received the response and no further information was requested in this area.

3. The proposed engagement with the Patient Advisory Panel should be undertaken and feedback provided around the nature of the activity, how the acceptability of using confidential patient information without consent was tested and how the study results should be disseminated. Feedback from the initial planned activity would be required prior to any final recommendation of support coming into effect.

The applicant provided detailed feedback from one patient panel member around their views on the work of the Group.

Members received the information. It was noted that a link the to the Cancer Survival Group's (CSG) website had been provided in response to point four below. On review of the website, the Sub-Committee considered the overview of patient engagement event which had been co-hosted by the CSG together with the National Cancer Research Institute's Consumer Forum (NCRICF) which was attended by 50 individuals with experience of cancer. This event was held in February 2017 and builds on a previous event which was hosted in 2012. The Sub-Committee was assured by this wider information and raised no further queries in this area.

4. Provide details of the communication strategy which is in place to promote the study in the public arena, together with any supporting documentation which will be used to facilitate this. Documentation should provide relevant links to the established objection mechanisms operated by the cancer registries.

This document was provided.

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)

- Favourable opinion from a Research Ethics Committee (Confirmed).
- Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (Confirmed – Cancer Survival Group at London School of Hygiene and Tropical Medical has a Standards Met Grade on DSPT).

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Name	Notes
Dr Tony Calland MBE	Chair
Dr Katie Harron	CAG Member
Ms Dianna Robbins	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title

MATTS (Major Trauma Triage Tool Study)

CAG reference

19/CAG/0119

IRAS project ID

254609

REC reference

19/YH/0197

Context

Purpose of application

This application from the University of Sheffield set out the purpose of medical research which aims to develop a new and more accurate triage tool to be used by paramedics when assessing patients for signs of major trauma.

The study is planned in three phases. The first phase will involve assessment of existing triage tools to evaluate how they perform. The applicants will also use a computer model simulates the costs and outcomes of using the different triage tools. The resulting information will be presented to a group of experts who will be asked to develop a new major trauma triage tool. This phase of the study will not involve any access to confidential patient information and is out of scope for the CAG application.

The best performing tools will then be introduced into an area of each of the ambulance service to test their performance in a real-life situation in phase two of the project. This is a prospective study which will involve research paramedics accessing ambulance records and hospital records to test the tools. A deterministic matching process will be used using ambulance identifiers to link records and will be supported by the local TARN administrator. The applicants are seeking support under the Regulations to legitimise access to hospital records by research paramedics, who will be assisting local Trauma August and Research Network (TARN) coordinators in identifying patients and extracting pseudonymised patient data to be used in analysis. Support is also sought under the Regulations to use pseudonymised patient information collected by the TARN with support under the Regulations via application ECC 7-05(g)/2011 for wider research purposes.

Phase three of the project will involve the implementation of the best performing tool at phase two into real life practice within the participating ambulance Trusts to enable an evaluation of the performance to be undertaken. This will follow the same methodology as phase two of the project and required ‘section 251 support’ to legitimise processing.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients of any age who are attended by Emergency Medical Services (EMS) following non-trivial injury within a participating trauma network across the following ambulance services, between November 2019 and February 2020. • West Midlands Ambulance Service • Yorkshire Ambulance Service

	• London Ambulance Service • South Western Ambulance Service
Data sources	Ambulance Computer Aided Dispatch (CAD) data Ambulance (Electronic)Patient Report Forms (PRFs) Hospital administrative systems Hospital Patient case notes
Identifiers required for linkage purposes	Computer-aided despatch reference Ambulance incident number Incident date/time Call sign numbers Age Gender Hospital destination
Identifiers required for analysis purposes	Gender Age at event Date and time of incident Date and time of arrival at destination hospital
Additional information	The first phase of the study involves access to retrospective pseudonymised data patient which is out of scope for the CAG application. Whilst the patient identifiers requested are not standard items of confidential patient information, there would be wider access to confidential patient information contained in patient records both within the Ambulance Trusts and Hospital records during the data extraction process.

Confidentiality Advisory Group advice

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

1. Using the National Data Guardian's definition as guidance, assess whether the research paramedics have been appropriately categorised as members of the clinical care team in the ambulance Trust environment. Provide assurance that this is correct, or specifically request that this access be considered within the scope of support being recommended within this application.

The applicant explained that the four Research Paramedics for the project would be directly employed by the participating ambulance services. These individuals would be experienced paramedics who are registered healthcare professionals (registered with the Health And Care Professionals Council). These individuals would all cover clinical shifts as and when is necessary for their respective Ambulance Services, and

as such, the applicant confirmed that these individuals were part of the clinical care team.

The CAG received the assurance from the applicant.

2. Explain how any project-specific dissent which was raised would be applied and respected within the study dataset.

The applicant explained that members of the public were able to contact the research team via the phone, website, study email, or twitter feed (all available online/posters in Hospitals and Ambulance Services to display details also) to lodge their dissent to participate. If an objection was received, the research team would aks for consent to use their personal details to ensure that the individual's data was not included or was removed from the dataset. With permission, personal identifiers would also be shared with participating ambulance services and the Trauma Audit and Research Network who would remove these cases prior to data transfer to Sheffield Clinical Trials Unit. The applicant will then retain personal details (with the individual's consent) until after the end of Phase 3 (to ensure they are not re-enrolled) and then destroy their personal details at this point.

Members received the explanation and were satisfied with the described process.

3. Clarify how ambulance Trusts and TARN coordinators within the hospital sites would be able to check for evidence of national opt-outs registered by patients.

The applicant confirmed that TARN and the participating Ambulance Services would be using the Message Exchange for Social Care and Health (MESH) system to check for any opt outs raised via the national opt out scheme. Checks would be run monthly during phases when the project was actively collecting data.

The CAG received the explanation and raised no queries 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

1. Favourable opinion from a Research Ethics Committee. Confirmed 28 June 2019.
2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. See section titled ‘security assurance requirements’ in the provisionally supported outcome for further information. Not checked due to the number of sites involved in the study. Support is recommended on the basis that it is the applicant’s responsibility to ensure that the required security assurance standards have been met at each site prior to processing any confidential patient information with support under the Regulations.

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Name	Notes
Dr Patrick Coyle	Vice-Chair
Dr Lorna Fraser	CAG Member
Mr Anthony Kane	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title

Realist Evaluation of Pressure Ulcer Risk Assessment Instruments in Clinical Practice: Theory Testing

CAG reference

19/CAG/0088

IRAS project ID

258489

REC reference

19/YH/0033

Context

Purpose of application

This application from the University of Leeds set out the purpose of medical research which aims to develop understanding of how risk assessment tools to assess pressure ulcers (PU) are used in clinical care.

Two tools will be assessed. The standard form is the Pressure Ulcer Risk Assessment (PU-RAI) forms, which help nurses to identify patients ‘at risk’ to prompt preventative measures (e.g. nursing care, mattresses). The Pressure Ulcer Risk Primary or Secondary Evaluation Tool (PURPOSE-T) was robustly developed/evaluated and has since been implemented in several NHS acute hospitals. A realist evaluation will be undertaken to understand how different

contexts influence particular nursing team responses and give rise to different outcomes when using PURPOSE-T and standard forms. The realist evaluation incorporates four phases; ward based theory testing, wider interviews with staff from other hospitals, a focus group held with the Pressure Ulcer Service User Network (PURSUN), and a guideline development stakeholder focus group.

The application to the CAG focuses on one element of the first project phase which will be undertaken prior to patients being approached for consent. The researcher will observe staff handover and ward meetings where patient details will be discussed, including medical details and care planned and delivered. The applicant will utilise these observations to identify and discuss patients who maybe potentially suitable to be approached for consent for the wider elements of the study.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients within the following treatment wards during the time of staff observations at each of the two participating Trusts. Eight wards will be included in the research observations, including two high-risk elderly medical wards (one admission, one medical) and two varied-risk adult surgical wards (one surgical admission, one general surgical).
Data sources	Observations of staff handovers and meetings held within Leeds Teaching Hospitals NHS Foundation Trust and Bradford Teaching Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	Not applicable – no confidential patient information will be accessed or recorded
Identifiers required for analysis purposes	Not applicable – no confidential patient information will be retained
Additional information	Confidential patient information will be disclosed during the observations of staff handover and ward meetings. Nothing

	will be recorded at this stage and is not required for the purposes of analysis.

Confidentiality Advisory Group advice

1. Confirm whether is the request for support under the Regulations was intended to cover the approach for patient consent for the direct patient observations.

The applicant confirmed that it was not intended for support to extend to this activity. This assurance was received.

2. If so, provide a stronger justification to support why this approach for consent cannot be made by the direct care team.

The applicant confirmed that it would not be appropriate for the direct care team to make the approach for patient consent as this was an observational study, and direct involvement would heighten staff awareness of the ongoing project, which may lead to changes in their normal clinical practice.

The response was received, and no queries were raised.

3. The poster document should be revised to provide detail around the potential for incidental disclosures of confidential patient information during the staff observations. This should provide details of how a patient can object to this element of the study.

The applicant provided an updated poster for review.

The Sub-Committee requested a further minor revision to the document to ensure that it was clear to readers that confidential patient information would not be recorded during observations.

The revised document was provided by the applicant and received by the CAG, no further queries were raised.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the 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 15 April 2019).
2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. (Confirmed: Leeds Teaching Hospitals NHS Trust and Bradford Teaching Hospitals NHS Foundation Trust have confirmed ‘Standards Met’ grade).

New amendments

Name	Notes
Dr Tony Calland MBE	Chair
Miss Kathleen Cassidy	Confidentiality Advisor

Application title

Learning Disabilities Mortality Review Programme

CAG reference

16/CAG/0056 (re-submission of 16/CAG/0005)

Amendment request

The applicant advised that the intended end date of the LeDeR programme had previously been 31 May 2019. The programme had since been extended to 31 May 2020, and the contract between HQIP and the University of Bristol for the delivery of the programme had been agreed.

The programme was funded by NHS England as part of a national suite of work aimed at reducing premature mortality and improving provision for people with learning disabilities. It was also part of the National Clinical Audit and Patient Outcome Programme, which Trusts are mandated to participate in as part of the standard NHS contract. As part of this, Trusts are required to review the deaths of people with learning disabilities in their care using the LeDer Methodology. The LeDeR programme was identified in the NHS Long Term plan, published in 2019, as being an initiative to reduce health inequalities for people with learning difficulties.

The applicants explained that there was a strong public interest in the Programme, as it was undertaken in the interests of improving patient care. Service improvements made as part of this programme were also likely to be relevant to other vulnerable groups. If continuing support was not given then a significant number of deaths already notified to the programme would not be reviewed, and the families of these patients would expect a review to be carried out. Further

information about the service improvements required to reduce the premature mortality of those with learning disabilities was also needed, and would not be collected if the programme ended.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that support under Section 251 and its Regulations should continue.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met 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 DSPT submission. Confirmed for University of Bristol – School of Policy Studies on 10 July 2019.

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Name	Notes
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title

Research to identify measures of quality and safety of healthcare

CAG reference

15/CAG/0005

IRAS project ID

167242

REC reference

10/H1102/25

Amendment request

The amendment request sought support to change the location of the server equipment which hosted the project database to a new Imperial College facility located at the Virtus data centre.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. It was noted that the described change of data storage location was an administrative change. The applicant had provided evidence of the relevant security assurance via NHS Digital email confirmation of ‘Standards Met’ grade for the Data Security and Protection Toolkit.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAT 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 Data Security and Protection Toolkit submission (Confirmed – Imperial College London, Faculty of Medicine, School of Public Health (Primary Care and Public Health, Dr Foster Unit).
2. Confirmation of a favourable opinion from a Research Ethics Committee (Confirmed).

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Name	Notes
Dr Tony Calland MBE	Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title

At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK (ARRISA-UK): A pragmatic cluster randomised trial with nested economic and process evaluations examining the effects of integrating at-risk asthma registers into primary care with internet-based training and support

CAG reference

18/CAG/0185

IRAS project ID

161432

REC reference

14/WA/1211

Amendment request

The amendment request detailed the following two changes to the study:

- Extension of cohort – to include patients registered at 10 Welsh GP practices which are close to the border, for whom it is envisaged that hospital admissions would occur in England.
- Wider linkage by NHS Digital – to extend the scope of mortality to information to all deaths, not just those specified as linked to asthma and all outpatients and critical care periods for the patients.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. It was recognised that the wider linkage of Welsh border practices would enable a complete case

ascertainment in relation to secondary care data to be achieved to inform more complete analysis. The extension to the mortality data will ensure all deaths are accounted for in analysis, not just those which have been coded as asthma-related. This together with the wider hospital admissions data will also inform a more complete analysis for the study. The Chair was content to provide a recommendation of support to the amendment.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via DSPT submission (Confirmed - NHS Digital and Harvey Walsh Ltd. have confirmed Standards Met grade on the DSPT 2019/20).
2. Confirmation of a favourable opinion from a Research Ethics Committee (Confirmed – Existing REC favourable opinion covers these changes).

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Name	Notes
Dr Tony Calland MBE	Chair
Miss 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

Amendment request

The amendment request sought support for the following two project changes:

- Retention of the patient's recorded frailty index score for the purposes of analysis
- Changes to the storage arrangements for the study back-up data, which will be held on a fully encrypted external hard drive, retained onsite at Leeds Teaching Hospitals NHS Foundation Trust.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The applicant had provided a clear justification to support the ongoing retention of the frailty index score for analysis purposes. It was explained that there was an ongoing debate about the balance between harms and benefits in patients classified as having moderate or mild frailty. In retaining this data for analysis, the applicant would be able to

undertake assessment at the trial end of participation rates amongst participants with different frailty scores. This would inform assessment of the interventions and potential benefits for participants diagnosed with lung cancer by screening according to frailty category. The CAG was assured that the ongoing retention of this data item supported the overarching public interest in the trial and was content to provide a recommendation of support.

The wider data retention arrangements were noted, and no queries raised in this area.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CA 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 DSPT submission (Confirmed: below organisations have confirmed Standards Met confirmed by NHS Digital email

- Leeds Teaching Hospitals NHS Foundation Trust (12/07/2019)
- University of Leeds - Integrated Research Centre (21/06/2019)
- CFH Docmail Ltd (19/07/2019)

2. Confirmation of a favourable opinion from a Research Ethics Committee (Confirmed – 24 June 2019)

Appendix 1. Confidentiality Advisory Group Sub Committee Minutes

Name	Notes
Dr Patrick Coyle	Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title

Liver transplantation as treatment for patients with hepatocellular carcinoma; a study using existing electronic data.

CAG reference

17/CAG/0025

IRAS project ID

218152

REC reference

17/LO/0231

Amendment request

The amendment is seeking support to re-run the data linkage between the National Cancer Registration Analysis Service (NCRAS, Public Health England) and the Hospital Episodes Statistics (HES, NHS Digital) datasets.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. It was recognised that this data linkage had previously been supported; however, it had been found that the analysis outputs were inaccurate.

Following discussion between the applicant, Public Health England and NHS Digital, it had been determined that there had either been an error with the initial data itself or the linkage process, which was the rationale supporting the re-run of this process. The CAG was assured by the overarching public interest in the application activity and recognised that accurate datasets were necessary for analysis.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via Data Security and Protection Toolkit submission (Confirmed - The Royal College of Surgeons of England, 08/07/2019 and NHS Digital have Standards Met grades).
2. Confirmation of a favourable opinion from a Research Ethics Committee (Confirmed – covered by existing REC favourable opinion).

Appendix 1. Confidentiality Advisory Group Sub Committee Minutes

Name	Notes
Dr Patrick Coyle	Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title

Renal Replacement Anticoagulation Management

CAG reference

18/CAG/0070

IRAS reference

236515

REC reference

18/SC/0204

Amendment request

The amendment has been submitted to extend the duration of support to 31 December 2019 for the application activities.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's action. It was noted that the duration extension was necessary to enable the final linkage process to be undertaken in order to create the pseudonymised dataset required for analysis.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via Data Security and Protection Toolkit submission (Confirmed: ICNARC and Oxford University

Hospitals NHS Foundation Trust have confirmed ‘Standards Met’ on DSPT via NHS Digital).

2. Confirmation of a favourable opinion from a Research Ethics Committee (Confirmed – Non-Substantial amendment confirmed 28 August 2019).

Appendix 1. Confidentiality Advisory Group Sub Committee Minutes

Name	Notes
Dr Patrick Coyle	Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title

Lung cancer screening study using low dose CT to support the development of blood tests for early cancer detection

CAG reference

18/CAG/0054

IRAS project ID

232691

REC reference

17/LO/2004

Amendment request

This amendment seeks to extend support to wider sub-contractors working on behalf of Grail Ltd., the organisation which facilitates and maintains the trial database, to undertake this maintenance work. The applicant has confirmed that the sub-contractors would be covered under the standard security arrangements and associated policies implemented by GRAIL Ltd.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group which reconsidered previous queries raised under the initial review of the application around the geographical base of contractors undertaking maintenance of the trial database. However, it was recognised that the data agreement document which had been provided by the applicant in support of the amendment provided the necessary assurance that all staff acting on behalf of Grail Ltd. who would undertake this

database administration would be UK-based. With this clarification, the CAG was assured that the proposed amendment should be supported.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via Data Security and Protection Toolkit submission (Confirmed – University College London has a confirmed ‘Standards Met’ DSPT submission)
2. Confirmation of a favourable opinion from a Research Ethics Committee (Confirmed within the scope of existing ethical opinion).

Appendix 1. Confidentiality Advisory Group Sub Committee Minutes

Name	Notes
Dr Tony Calland	CAG Chair
Miss Kathleen Cassidy	Confidentiality Advisor

Application title

Learning Disabilities Mortality Review Programme

CAG reference

16/CAG/0056 (re-submission of 16/CAG/0005)

Amendment request

The applicant advised that the intended end date of the LeDeR programme had previously been 31 May 2019. The programme had since been extended to 31 May 2020, and the contract between HQIP and the University of Bristol for the delivery of the programme had been agreed.

The programme was funded by NHS England as part of a national suite of work aimed at reducing premature mortality and improving provision for people with learning disabilities. It was also part of the National Clinical Audit and Patient Outcome Programme, which Trusts are mandated to participate in as part of the standard NHS contract. As part of this, Trusts are required to review the deaths of people with learning disabilities in their care using the LeDer Methodology. The LeDeR programme was identified in the NHS Long Term plan, published in 2019, as being an initiative to reduce health inequalities for people with learning difficulties.

The applicants explained that there was a strong public interest in the Programme, as it was undertaken in the interests of improving patient care. Service improvements made as part of this programme were also likely to be relevant to other vulnerable groups. If continuing support was not given then a significant number of deaths already notified to the programme would not be reviewed, and the families of these patients would expect a review to be carried out. Further information about the service improvements required to reduce the premature

mortality of those with learning disabilities was also needed, and would not be collected if the programme ended.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that support under Section 251 and its Regulations should continue.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met 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 DSPT submission. Confirmed for University of Bristol – School of Policy Studies on 10 July 2019.

Appendix 1. Confidentiality Advisory Group Sub Committee Minutes

Name	Notes
Dr Murat Soncul	Alternate Vice Chair
Miss Kathleen Cassidy	Confidentiality Advisor

Application title

Genetic mechanisms in polyposis of the bowel.

CAG reference

17/CAG/0011

IRAS project ID

87399

REC reference

12/WA/0071

Amendment request

The applicants had initially applied for support under Section 251 and its Regulations to include a cohort of deceased patients. The number of deceased patients was capped at 20, and the applicants have confirmed that this number will not be exceeded. So far, the applicants have recruited 10 deceased patients and are seeking support to extend the end date of the study until 31 August 2020, to allow more time to meet the recruitment target.

The applicants intend to recruit 350 patients into the entire cohort, and are also extending the timescale of the study so that this target is met. However, living patients are consented into the study, and are outside the scope of the application for Section 251 support.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The rationale for extending the duration of the study was accepted.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via Data Security and Protection Toolkit submission confirmed for Cardiff University
2. Confirmation of a favourable opinion from a Research Ethics Committee confirmed 07 August 2019