Health Research Authority

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

June 2021

1. New Applications

a. 21/CAG/0070 - The DAMPen-D study: Improving the Detection, Assessment, Management, and Prevention of Delirium in Hospices - Co-design and feasibility study of a flexible and scalable implementation strategy to deliver guideline-adherent delirium care

Name	Capacity
Dr Martin Andrew	CAG member
Dr William Bernal	CAG alternative vice-chair
Ms Sophie Brannan	CAG member
Mr David Evans	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Ms Diana Robbins	CAG member
Mr Umar Sabat	CAG member

Dr Murat Soncul	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Hull set out the purpose of medical research that seeks to establish whether it is feasible to collect sufficient outcome data, explanatory process data, and cost data, in a future effectiveness evaluative study in palliative care settings.

It is common for people to suffer from acute confusion, or delirium, towards the end of their life, which can be distressing for those with delirium, and their friends, family and carers. Treating delirium can also cause anxiety and stress for the health professionals who are trying to manage the delirium effectively. The applicants noted the importance of improving how delirium is assessed, prevented and managed within hospices. Guidelines for improving delirium care have been issued by the National Institute for Health & Care Excellence, the Scottish Intercollegiate Guidelines Network, and the Australian Commission on Safety & Quality in Health Care, however research shows that less than half of palliative care doctors use delirium guidelines. Delirium screening tools are infrequently used, yet there is no research about how to improve the implementation of delirium guidelines and tools in day-to-day practice. The applicants seek to address this by conducting a feasibility study to assess the usefulness of the CLECC-Pal implementation plan in day-to-day use of guideline-recommended clinical care, and whether, under these circumstances, the number of delirium days suffered by patients is reduced in a cost-effective manner. The applicants will also be assessing whether a larger-scale study can be run. The study is comprised of 3 work packages. Work Package 1 involves engagement with stakeholders. Work Package 3 is a process evaluation, where staff and volunteers will take part in surveys. Work Packages 1 and 3 are outside the scope of REC review and the support sought under Regulation 5.

The study will be conducted in three non-NHS inpatient hospice units in Yorkshire. The hospices will be supported by the study team in using the CLECC-Pal plan to implement guideline recommended delirium care over a minimum of 12 weeks. At sites 1 and 2, paper case records will be accessed by the research team. The hospice staff will identify 50 consecutive patients who were admitted to the hospice before the CLECC-Pal was used in the hospice. The researcher will then access the patient records to extract anonymised data. Each documented case of delirium will be assigned a unique identifier number by the researcher (the study ID), which will be used internally by the research team to identify individual episodes of delirium. This unique identifier will not be used to link the extracted data back to the clinical records, as no key is retained. The same process will be repeated for 12 weeks after the implementation of the CLECC-Pal at the site. Site 3 has electronic patient records only. This computer will be located in a GP practice in Hull. As at sites 1 and 2, hospice staff will identify 50 consecutive patient records preceding the date CLECC-Pal (the intervention) was introduced to the hospice. Hospice staff will email the patients NHS number to the researcher via secure NHS email, in order for the researcher to be able to identify the patient on SystmOne.

The researcher will then access the patient records on SystmOne remotely via a secure NHS GP surgery computer located at a GP surgery in Hull and extract an anonymised dataset. Only pseudonymised data will be uploaded to the study records, on the University of Hull laptop, and this can be considered anonymous to the applicants.

A recommendation for class 1, 2 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 aged 18 years and over who are receiving inpatient palliative care at the three participating hospices (50 consecutive patients from each hospice, over 2 time periods, so 100 total per site.)
Data sources	1. Paper records held at 2 participating hospices Dove House Hospice, Hull St Leonards Hospice, York 2. Electronic records held at the third participating hospice: Marie Cure, Bradford, which will be accessed on University of Hull encrypted laptop at James Alexander Family practice, Hull
Identifiers required for data extraction for paper records at 2 participating hospices	1. Age 2. Sex 3. Ethnicity 4. Unit level Postcode (converted to multiple deprivation index at extraction) 5. Unique study ID – allocated by the researcher at point of extraction 6. Patients medical records will be viewed
Identifiers required for data extraction from SystmOne at 1	1. NHS number (in order to identify patient on SystmOne) 2. Age

participating hospices	3. Sex 4. Ethnicity 5. Unit level Postcode (converted to multiple deprivation index at extraction) 6. Unique study ID – allocated by the researcher at point of extraction 7. Patients medical records will be viewed
Identifiers required for analysis purposes	1. Age 2. Sex 3. Ethnicity 4. Unique study ID This can be considered anonymous to the researchers.

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. **Please provide the favourable opinion from the REC when available.**

The applicant provided a favourable opinion from the REC to the CAG inbox on 3rd June.

2. **Please provide an updated patient notification which contains a lay explanation of the term anonymous, and is explicit in describing the access the researcher is permitted to have regarding medical notes.**

The applicant provided an updated poster which responded to the elements requested by CAG. The Sub-Committee reviewed this notification and were content that this was now sufficient, and were content to now recommend support.

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 28 May 2021.

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 below titled 'security assurance requirements' for further information. Confirmed

   Security assurances are required for the 5 sites where processing of confidential patient information will take place. Support will be based on confirmation that the DSPT at the site will be complied with. However, as this is 5 or more organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.

The organisations involved are:

University of Hull - Hull Health Trials Unit (EE133824-HHTU)

Dove House Hospice, Hull

St Leonards Hospice, York

Marie Cure, Bradford

James Alexander Family practice, Hull

b. 19/CAG/0044 - Evaluating the two-week wait referral system for bowel cancer

Name	Capacity
Ms Sophie Brannan	CAG member
Dr Harvey Marcovitch	CAG member
Ms Diana Robbins	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Dr Paul Mills	Confidentiality Advice Service Manager

Context

Purpose of application

This application from London School of Hygiene and Tropical Medicine set out the purpose of medical research which sims to understand whether the two-week wait (TWW) urgent GP referral system had provided any benefits for patients with suspected colorectal cancer. The two-week wait system was introduced as part of the 2000 NHS Cancer Plan and aimed to expedite pathways for diagnosis and treatment of cancer in England.

The applicant intends to examine whether the two-week wait is associated with improvements in diagnostic investigation, stage distribution, treatment and short-term mortality. Innovative analytical techniques will be used to consider what would have happened to patients diagnosed through the two-week wait system in terms of cancer outcomes, had they been diagnosed through a non-urgent referral. All patients referred by their GP to the colorectal surgical outpatient clinics in Portsmouth Hospitals NHS Trust since 1986 will be identified and linked with wider clinical information held by the National Cancer Registration and Analysis Service (NCRAS) at Public Health England, Hospital Episodes Statistics held by NHS Digital and the National Bowel Cancer Audit, which is commissioned by the Health Quality Improvements Partnership (HQIP) and carried out by NHS Digital, in order to carry out the 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	All patients referred to Portsmouth Hospitals NHS Trust for suspected bowel cancer between 1986 and 2017.
Data sources	Portsmouth Hospitals NHS Trust
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Date of death 4. Postcode (District Level) 5. Sex
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode 4. Sex

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. **Clarify the start and end dates of the inclusion timeframe for the patient cohort in DD/MM/YY format.**

The applicant confirmed that the timeframe for inclusion is 01 January 1986 to 31 December 2017. The CAG noted this and raised no further queries.

2. **Provide an estimate of the patient cohort size.**

The applicant advised that, between 1986 and 2007, a total of 26,972 patients without a history of colorectal cancer were referred to the clinic for endoscopic investigation, some more than once. Of these, 1,626 patients were newly diagnosed with colorectal cancer.

The database is being updated with information on patients referred to the clinic up to 31 December 2017. It was anticipated that the number of patients diagnosed with colorectal cancer will rise by about 50%, to 2,400 patients approximately, assuming constant incidence rates. The number of referrals will rise proportionately, perhaps to a total of 40,000, given that the threshold for referral is now less restrictive. The CAG noted this and raised no further queries.

3. **Submit a clear data flow chart which provides a clear overview of the proposed data flows within the project, highlighting where confidential patient information is being disclosed between organisations to facilitate linkage with wider NHS datasets.**

The applicant provided a data flow chart. This set out that the linked dataset, held by the Cancer Survival Group, included patient identifiers for linkage purposes. These were held with CAG support under the reference PIAG 1-05(c)/2007. This dataset will be linked to the Portsmouth Database, after which the identifiers will be removed, resulting in an anonymised dataset of patients with colorectal cancer diagnosed in the referral clinic. The CAG reviewed the provided dataflow diagram and raised no further queries.

4. **Clarify when confidential patient information would be deleted by all organisations processing within the scope of the project to establish an exit strategy from the requirement for support under the Regulations.**

The applicant advised that confidential patient information will not be disclosed under any circumstances during this project, and no other organisation will be involved in the data linkage. The individual will be retained, but only after de-identification, to enable independent re-analysis in the event of challenges to the credibility of the analysis or accusations of fraud or scientific misconduct. The International Committee of Medical Journal Editors states that investigators have a duty to maintain the primary data and analytic procedures underpinning the published results for at least 10 years.

The CAG further clarified when confidential patient information would be deleted by all organisations processing within the scope of the project and requested further information on whether any items of confidential patient information would be retained after the linkage has taken place, or will all items of confidential patient information be deleted. If the items would be deleted, the CAG queried how long after the data linkage will the deletion occur, whether a link file would be retained and whether the London School of Hygiene and Tropical Medicine responsible for the deletion.

The applicant responded to confirm that no identifiable data will be retained after linkage and will be delated six months after linkage. A key will be retained, but this will only enable Portsmouth Hospitals NHS Trust to re-identify. This further response satisfied the CAG.

5. **Patient and public involvement and engagement activity should be undertaken to test the acceptability of using confidential patient information without consent to achieve the proposed study aims. Provide information about the activity which was undertaken, together with the demographics of the group involved, together with an overview of the feedback which was required.**

We will take the Committee's advice to organise the necessary PPI activities with an established patient group within the Portsmouth Hospitals NHS Trust to understand patients' views on this project and test the acceptability of using confidential patient information without consent for this specific research question.

Co-investigator Sara Benitez Majano will discuss the research project at the next Patient Research Ambassadors meeting, organised by Sharon Court, Patient and Public Involvement Facilitator at Portsmouth Queen Alexandra Hospital, scheduled for 27 January 2020.

The Cancer Survival Group is actively involved in patient engagement with our research. We were awarded Special Recognition for Patient Involvement in Research by Cancer Research UK in 2017, with the citation "for [our] sector-leading working involving people affected by cancer in the design and delivery of cancer research". Cancer patients sit on two of our advisory panels, on which they comment on our research at one-day or two-day meetings. We attend meetings of the National Cancer Research Institute Consumer Liaison Group. Some members of the Consumer Liaison Group write letters of support for our research grant applications. Patients appear in three of the home-page images on our web-site https://csg.lshtm.ac.uk/. Finally, this project is actually funded by a bowel cancer charity that is run by cancer patients.

Members reviewed the provided information and noted that the bulk of the answer referred to more general patient and public involvement work, rather than exploration of the use of confidential patient information as proposed for this specific project. Following further discussions with the applicant, CAG were provided with comments from members of the patient and public involvement group.

Members were content with these responses, requesting an update on continued patient and public involvement at the first annual review.

6. **A communications mechanism should be established to promote the proposed activity in the public domain and to offer a means for patients to raise an objection to the use of their data in this study. Provide an overview of this mechanism together with copies of any documentation which would be used to facilitate this.**

The applicant advised that a lay summary of this project would be produced and made available to current patients attending the oncology department and two-week-wait clinics. This will include a link to the Cancer Survival Group website and a contact address for anyone who wishes to object to the use of their data. A Patient and Public Involvement Facilitator, Patient Research Ambassadors and a Research Facilitator had assisted in the creation of the lay summary.

Members reviewed the lay summary and requested that a telephone number was provided in addition to the email address, for patients to contact to opt-out. The CAG also asked that the opportunity for opt-out also was made more prominent and that the 'If you have any comments...' text was changed to 'If you would like to opt-out or if you have any comments…'

These updates were made and members were content.

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

The following sets out the specific conditions of support.

1. Provide an update on continued patient and public involvement that is undertaken at the first annual review.

2. Favourable opinion from a Research Ethics Committee (Confirmed 02 April 2019).

3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit (DSPT) submission (Portsmouth Hospitals NHS Trust (by check of the NHS Digital DSPT tracker on 16 June 2021) and the Cancer Survival Group – London School of Hygiene and Tropical Medicine (by check of the NHS Digital DSPT tracker on 16 June 2021) have confirmed 'Standards Met' grade on DSPT submission 2019/20.

c. 18/CAG/0187 - Project to Enhance ALSPAC through Record Linkage (PEARL): Phenotypic enrichment of the ALSPAC original parent/carer (G0) cohort through linkage to primary care electronic patient records and other databases.

Name	Capacity
Dr Malcolm Booth	CAG Expert Member
Dr Patrick Coyle	CAG Vice Chair
Professor Barry Evans	CAG Expert Member
Dr. Liliane Field	CAG Lay Member
Dr Lorna Fraser	CAG Expert Member
Mr Anthony Kane	CAG Lay Member
Mr Andrew Melville	CAG Lay Member
Ms Clare Sanderson	CAG Expert Member
Dr Murat Soncul	CAG Alternate Vice-Chair
Ms Gillian Wells	CAG Lay Member
Ms Katy Cassidy	REC Manager (HRA Internal Observer)
Miss Kathryn Murray	Senior Confidentiality Advisor
Dr Tony Calland MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from ALSPAC at the University of Bristol set out the purpose of medical research which aims to follow-up the parents and carer cohort (referenced as Generation 0 within the application) of the Avon Longitudinal Study of Parents and Children (ALSPAC) study via NHS administrative datasets held by NHS Digital, together with records held at local Trusts and primary care data from GP practices.

The Avon Longitudinal Study of Parents and Children (ALSPAC) is a three-generation cohort study with >15,000 enrolled participant families. Comprising the G0 generation cohort of pregnant women who lived in Bristol in 1991/92 and the fathers/partners; the G1 generation of children born in 1991/92 cohort; and the G2 generation of G1 offspring. All generations have provided information in questionnaires, study clinic assessments, through gifting biological samples and linkage to routine records. To obtain ALSPACs full value further follow–up is needed to explore research questions relating to the G0's health and wellbeing as they age and to investigate how exposures to G0 parent/carers interactions with the long-term outcomes in

G1. Extending linkage to health records provides a cost-effective means of data collection with low participant burden.

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

Confidential patient information requested

Cohort	All enrolled parents and carers recruited to the ALSPAC study, known as 'Generation 0' (G0). This includes approximately 15,500 G0 mothers and ~3,500 G0 fathers/partners.
Data sources	1. ALSPAC administrative database 2. NHS Digital datasets: 3. Personal Demographics Service (PDS) 4. Hospital Episode Statistics (HES), 5. Office for National Statistics (ONS) Mortality dataset 6. Mental Health Minimum Dataset (MHMD) 7. Mental Health and Learning Disabilities Data Set (MHLDDS) 8. Mental Health Services Data Set (MHSDS) 9. Emergency Care Data Set (ECDS) 10. North Bristol NHS Trust, local records 11. Royal United Hospitals Bath NHS Foundation Trust, local records 12. Primary Care information is received from GP practice providers via the SAIL databank, (which only handles pseudonymised data and applicant confirms does not require a recommendation of support) 13. University Hospitals Bristol and Weston NHS Foundation Trust, local records (currently provisionally supported only due to an outstanding DSPT – an updated support letter will be provided once security assurances are in place)

Identifiers required for linkage purposes	1. Name – sample validation and linkage 2. NHS Number – sample validation and linkage 3. Hospital ID Number – sample validation and linkage 4. GP registration – sample validation and linkage 5. Date of birth – sample validation and linkage and analysis 6. Postcode – sample validation and linkage and analysis
Identifiers required for analysis purposes	1. Date of birth – analysis 2. Postcode – analysis 3. Date of death – analysis 4. Sex – analysis 5. Ethnicity – 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.

1. **Clarify whether there has been any historic approach to consent participants for the proposed data linkage. If not, supporting documentation should be revised to ensure the terminology accurately reflects any attempts to contact patients.**

The applicant confirmed that there have not been any historical approaches to explicitly consent the ALSPAC G0 participants for data linkage. The language in the cover letter, objection form, GP assent request letter and GP information booklet has been revised to ensure the correct terminology is used. The protocol has also been amended.

The CAG Chair and Alternate Vice-Chair were content with this response, and the updated materials. It is noted that in some of the documents there are references to the Secretary of State in relation to the CAG, and the applicant is reminded that these references are not correct as this application has instead been supported by the Health Research Authority (HRA).

2. **Provide further details around the referenced prospective consent programme to clarify whether this approach was intended to be a formal consenting programme.**

The applicant has confirmed that this application consists of;

a. a fair processing notification describing the intended use of health records for research and describing the right to opt-out and the means by which this can be done. This fair processing is linked to this request for 'Section 251' support. The applicant has confirmed that this is not designed to gain consent and rather sets out ALSPAC's intention to use health records in our programme and to provide a means to object.

b. Consideration of appropriate 'exit routes' from using 'Section 251' support by seeking the explicit consent (to meet the terms of Common Law Duty of Confidentiality) of a participant for the use of their health records at the point where this becomes practicable (e.g. when a participant attends a study assessment clinic). The applicant has confirmed that ALSPAC recognise that implementing this 'exit route' will result in 's251' support not being applicable for that participant going forward.

Regarding the exit strategy, the applicant agrees that consent can only be for the onward retention of existing data and future collection of data, not for the retrospective collection of data. Patient notification have been amended to reflect this. The applicant has also agreed that where a participant is asked to formally consent to the study's use of their records then following an expression of dissent or non-response the 'Section 251' provisions can no longer apply for that individual.

The Chair and Alternate Vice-Chair were content with these responses.

3. Further information is required around the additional 1,000 patients who have been recruited to the study since initial enrolment. Provide further information around who this group is and how they were recruited, together with clarification around whether this sub-cohort is also included within the scope of support requested via this application.

For context regarding the applicants response, ALSPAC study participants were consented from an eligible population comprising any woman who was pregnant while living in and around the city of Bristol and due to deliver between 01 April 1991 and 31 December 1992. The study involved three generations:

G0: the original pregnant women, the biological fathers and non-biological carers

G1: the original index children

G2: the children of the original index children

A separate application under reference ECC 1-05(b)/2012 relates only to the G1: Index Children.

The applicant explained that this group of 1000 participants were eligible to participate in the study under the original study eligibility criteria and have enrolled into ALSPAC over time under the approved protocols of the time. They are not treated as a sub-group, and are considered to have the same enrolment status as any other enrolled participant.

'who this group is'

Pregnant women – the G0 mothers - were eligible to enrol into ALSPAC if they were resident in or around the City of Bristol and due to deliver between 01 April 1991 and 31 December 1992. It was determined at the time of recruitment that the fathers/partners of these women would be asked to participate but would not be asked to directly enrol. ALSPAC have established that there were 20,248 pregnancies which met these eligibility criteria, with a slightly smaller number of unique women given that some had multiple pregnancies in the time window. During the original recruitment process women carrying 14,541 of these pregnancies enrolled, either in pregnancy or shortly after birth (72% recruitment rate). The eligible cohort of 20,248 pregnancies is fixed. However, it is ALSPAC's policy that any eligible participant may enrol into the study at any time: an option which approaching 1,000 G0 mothers have subsequently taken up.

'how they were recruited'

The original recruitment was undertaken by midwives at routine appointments and by study staff at the delivery wards. There was also a widespread publicity drive to raise awareness of the study and to ask pregnant women to contact the study to enrol. In total, 14,541 pregnancies were enrolled during this campaign. At child age seven, ALSPAC contacted eligible participants not previously enrolled or dissented to ask for consent. G0 and G1 participants from 452 original pregnancies enrolled during this campaign.

Subsequently, G0 and G1 participants from 254 additional eligible pregnancies have enrolled. These enrolments were not in response to a systematic campaign and were largely resulting from direct approaches from the mothers to the study. These approaches were driven by a range of factors, e.g. a desire to contribute to the public good, that their friend was a study participant, in response to media stories etc.

ALSPAC has also approached G0 father/partners and asked them to enrol in their own right. This took place via postal mailings sent to the mother, or during the G0 father/partner study assessment visit. To date, ~3,500 G0 father/partners have directly enrolled into the study. None of these approaches included requests for G0 mother/father/partner(s) to consent for the use of routine health records.

'whether this sub-cohort is also included within the scope of support requested via this application'

The applicant explained that this application is seeking 's251' support to access health records of all enrolled G0 mothers and the ~3,500 enrolled fathers/partners. It does not seek support for any eligible participant who is not enrolled or who declined to enrol or for participants who enrolled and subsequently withdrew. The support requested therefore includes those enrolled during the initial recruitment campaign and those 1000 participants who enrolled at a later date.

The CAG Chair and Alternative Vice-Chair accepted this response.

Mental health datasets

It was noted by the Chair and Alternate-Vice chair that a condition had been applied in the provisional letter regarding access to sensitive data fields including information about mental health. The condition stated that access to mental health data is not supported under this

application. This condition has been removed. Linkage to mental health datasets is supported, as listed in the data sources, and no separate application is required.

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

The following sets out the specific conditions of support.

1. Support extends to the linkage and access to confidential patient information held within the registry datasets and personal demographics information cited in the application. Support does not extend to those items/data sources that are not clearly confidential patient information. It is the responsibility of the applicant, together with NHS Digital, to determine which of the specific data items requested would fall within the legal definition set out in the NHS Act 2006. An alternative legal basis would need to be established for information which does not fall within the legal definition set out in the NHS Act 2006.

2. Favourable opinion from a Research Ethics Committee (Confirmed – 31 August 2018).

3. 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.

   Confirmed: The NHS Digital 19/20 DSPT review for ALSPAC, NHS Digital, North Bristol NHS Trust and Royal United Hospital Bath were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 29 April 2021)

   Pending: The NHS Digital 19/20 DSPT review for UNIVERSITY HOSPITALS BRISTOL AND WESTON NHS FOUNDATION TRUST is pending, and an updated support letter will be provided once security assurances are in place. Support is not currently in place for any data flow regarding this organisation.

d. 21/CAG/0050 - Suicide in former service personnel: rates, antecedents, and prevention

Name	Capacity
Dr William Bernal	CAG alternative vice-chair

Dr Malcolm Booth	CAG member
Mr David Evans	CAG member
Mr. Myer Glickman	CAG member
Ms Diana Robbins	CAG member
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to investigate suicide risk amongst those who have left the UK Armed Forces, and to make comparisons with serving personnel and the general population.

Suicide accounts for almost 6,000 deaths per year in the UK and prevention is a health priority. Previous international studies have examined the incidence of suicide in former military service personnel, as well as risk factors associated with suicide. Studies in the United States have shown veterans to have a higher rate of suicide compared to the US general population. Increased risks have been found in men, those with depression or alcohol-related problems, as well as those subject to early discharge. A previous study conducted by the applicants had found that 224 veterans died by suicide within a cohort of 233,803 individuals who had left the UK Armed Forces between 1996 and 2005. Although the overall rate of suicide was not greater than that in the general population, the risk of suicide in men aged 24 years and younger who had left the Armed Forces was approximately 2 to 3 times higher than the risk for the same age groups in the general and serving populations. The risk of suicide for men aged 30-49 was lower than that in the general population.

Since this study was carried out, there has been no systematic investigation of suicide in UK veterans. It has been suggested that these individuals may be a potentially vulnerable group because of prior adverse life events, the difficulties associated with the transition to civilian life and high rates of homelessness and alcohol and substance misuse. The UK Armed Forces is just ending a period of very intensive operations. A range of new services for veterans may have improved access to mental health care. There is potentially greater public awareness and reduced stigma associated with mental health problems. In the general population, men in mid-life are now the group at highest risk of suicide. The applicants seek to undertake a new study to examine suicide in those who have left the UK Armed Forces to provide information to be used to inform preventive efforts.

The study will consist of two phases;

Phase 1 - the applicants will conduct a retrospective UK-wide cohort study. The data flow is:

- The Ministry of Defence will transfer data from the Service Leaver's Database (SLD), which does not contain patient information, to the NCISH research team.

- The applicants will link the SLD data to the NCISH general population suicide database, in order to identify patients who died by suicide/undetermined death.

- The data for those who could not be linked to the NCISH general population dataset, i.e. those who are still alive or who died by means other than suicide, will be deleted.

- The linked dataset will be pseudonymised at this point and a unique identifier applied.

- The unique MoD number and unique NCISH identifier will be transferred to the MoD so that the MoD can include additional data fields relating to demographics and military service from MoD SLD and healthcare from MoD data on this "suicide cohort". The dataset will then be pseudonymised.

- The MoD will also create a new dataset, using the SLD, where they will remove the "suicide cohort" from the SLD. This new, anonymised dataset will contain data on demographics, military service and healthcare from MoD data for living discharged personnel and discharged personnel who died by other causes. No identifiers will be included in this dataset. The MoD will also provide the NCISH with an extract from the MoD Deaths database for all in-service deaths from suicide or probable suicide in service personnel between 1998 and 2018.

- The NCISH research team, using a mixture of identifiers, will link this data to NCISH's general population suicide database. The general population suicide database includes a unique identifier that links NCISH general population suicide data to NCISH data on patient suicide deaths.

- Once linkage is complete all identifiers will be removed from the linked data, and unlinked data will be deleted.

- The pseudonymised dataset will be linked to NCISH's database of suicide deaths in people in recent contact with mental health services (patient suicides) using an existing unique NCISH identifier.

Phase 2 – the applicants will collect data on the factors related to suicide from other official source, such as coroner's records, for veterans who died by suicide. The applicants will apply random sampling to identify 200 patients from the dataset of veterans who died by suicide between 2007 and 2018. The applicants will then contact the relevant coroner by letter, which will include the patients name, date of birth and date of death, to request any information they have on that individual. This request will include audio copies of the inquest recordings, which are usually on CD but other formats will be requested if possible, from the Senior Coroner of the jurisdiction where the death occurred. If audio recordings are not available, the applicants will request copy statements or depositions and other relevant reports, such as post-mortem and toxicology reports, submitted as evidence during the inquest.

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

Confidential patient information requested

Cohort	Phase 1: 415,000 patients aged 16 years and over who are former service personnel of the UK Armed Forces, who died by suicide or probable suicide between 01 January 1996 and 31 December 2018. Phase 2: 200 patients aged 16 years and over who are former service personnel of the UK Armed Forces, who died by suicide or probably suicide between 01 January 2007 and 31 December 2018.
Data sources	Phase One 1. From the Ministry of Defence: The Service Leaver's Database, Deaths Database, Additional MoD data on education status, medical deployability status at exit, history of unlawful activity, disciplinary actions including military prison, whether failed a compulsory drug test, tariff descriptor for AFCS claims, marker for whether treated in Department Community Mental Health (DCMH), and mental health diagnosis if treated in DCMH. 2. From the National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH), held by the University of Manchester: General population suicide database, Patient suicide database Phase Two 1. Coroner inquest records, obtained from the Senior Coroner of the jurisdiction where the death occurred
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Date of death 4. Postcode – unit level 5. Place of death

	6. Gender
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – district level 4. Gender 5. Ethnicity
Additional information	The Department Community Mental Health (DCMH) service are an outpatient mental health service for serving personnel of the Armed Forces. They are commissioned by the MoD and run by the NHS.

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. **Clarify whether support is needed for the disclosure of patient information from the coroners to the University of Manchester.**

The applicants confirmed that support is not required for the disclosure of patient information from the coroners to the University of Manchester as a legal basis is provided under section 27(2) of the Coroners Regulations.

The CAG were content with this response.

2. **Provide a stronger justification on why consent cannot be sought from the living veterans whose information will be processed.**

The applicants noted that identifiable information from living veterans is not processed as part of this application. Nevertheless the applicants advise consent cannot be sought for the use of their deidentified data given that the University of Manchester has no contact details, the cohort will be over 400,000 which creates resource issues, and the return/non-return of consent will introduce bias.

The CAG accepted this justification.

3. **Advise whether full dates of birth and death need to be retained, or whether these can be rendered less identifiable.**

The applicants confirmed that date of birth and death from data supplied by the MoD will be removed and only the year of birth and year of death will be retained once data linkage is complete. In order to carry out survival analysis, the applicants will create a new variable indicating the number of days between leaving service and death.

Members were content with this response.

4. **The patient notification materials need to be improved.**

The applicants provided project specific notification based on previously supported studies. These were reviewed by the NHSE Patient and Public Voice group (including a relative bereaved by the suicide of a veteran), the Centre for Mental Health and Safety's Lived Experience Advisory Panel and to a veteran of the Armed Forces. The notification will be posted on the NCISH and MoD websites and freely available.

No further comments were raised by the CAG.

5. **Further efforts need to be made to inform veterans and their relatives that the research is taking place.**

In addition to the response in point 4, the applicants will convene a study reference group, who will be asked to disseminate the information in their networks. Additionally, the applicants will ask The Confederation of Service Charities to publish the information, as well as publicising on twitter.

The CAG were content with this response.

6. **Further patient and public involvement needs to be carried out, particularly around the processing of confidential patient information without consent as proposed in the application and around improvements to the patient notification materials.**

Further patient and public involvement was undertaken with sought comments and feedback from members of the NHSE Patient and Public Voice group (including a relative bereaved by the suicide of a veteran), the Centre for Mental Health and Safety's Lived Experience Advisory Panel and a veteran of the Armed Forces, which included discussion on the use of identifiable data without consent. Responses were supportive of the study.

The CAG had no further concerns in this area.

7. **An explanation on how the National Data Opt-Out would be applied is required.**

The national data opt out is applied as part of the wider NCISH work, and data for those that opted out will not be contained within the NCISH database.

No further concerns were raised by the CAG.

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

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. Confirmed 16 December 2020.

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: The NHS Digital 2019/20 DSPT review for The National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (16 April 2021).

e. 21/CAG/0035 - ABC Discover (Molecular Phenotyping of Breast Cancer)

Name	Capacity
Dr William Bernal	CAG alternative vice-chair
Ms Sophie Brannan	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from the University of Southampton sets out the purpose of medical research that seeks to determine how diet and environmental factors influence breast cancer patient outcomes.

The follow-up of cancer patients previously involved in research is undertaken in order to detect any recurrence of cancer as early as possible, with the aim of enabling rapid

treatment provision. Due to improvements in treatment of cancer, many patients live longer. Extended follow-ups are undertaken to detect what may influence cancer recurrence, what causes progression and the eventual time to death.

The applicants are seeking support to use confidential patient information collected for the DietCompLyf study to investigate how diet and environmental factors influence breast cancer patients' outcomes and to compare disease-free long-survival patients with those showing cancer progression. The DietCompLfy study was a prospective observational study, which recruited patients between 1997 and 2010 and closed in 2015, and examined the relationship between diet and lifestyle and breast cancer recurrence and survival rates in the UK.

The DietCompLfy was originally sponsored by University of Westminster, but the CI and sponsorship subsequently moved to University College London. However all data remained with University of Westminster and never moved.

This separate, subsequent study seeks to transfer the data to University of Southampton to assimilate the data and link with HES data at NHS Digital. Participants consented to linkage with the predecessor of NHS Digital, but the applicants consider this not to be sufficient for linkage as consent to do so was for a separate study. Following completion of linkages all identifiers will be deleted and anonymised, at which point support will no longer be required.

A recommendation for class 1, 2 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	Female patients aged 16 years and over who were recruited into the DietCompLyf study. 3390 will be included.
Data sources	1. Patient records from the DietCompLyf study, held at University of Westminster 2. Paper study diaries and questionnaires, held by University of Westminster (note these do not contain identifiable data but may be sent with the identifiers) 3. HES 10-year mortality/morbidity data is held by NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number

	4. Date of birth 5. Date of death 6. Postcode – unit level
Identifiers required for analysis purposes	1. Date of death 2. Postcode – district level 3. Gender 4. Ethnicity

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. **A data flow diagram, setting out the flows of confidential patient information and pseudonymised or anonymised information, and the organisations involved, needs to be provided.**

A data flow diagram was provided. Following clarification and further update regarding flows of data back to University of Westminster CAG members accepted the flow diagram.

2. **Clarify whether patient notification will be undertaken at the 56 trusts that participated in the original study. If not, members agreed that notification should be undertaken at these trusts and details on the notification mechanism provided to the CAG.**

The applicants stated that they have details of the 56 Trusts and will make contact with them to display the patient notification. The CAG were content with this response.

3. **The following changes are to be made to the study poster:**

    a. **The language used needs to be simplified.**
    b. **The poster needs to explain the new study and the linkages of hospital data to NHS Digital datasets.**
    c. **The National Data Opt-Out needs to be referenced as well as local opt out mechanisms.**
    d. **Email, telephone and postal contacts need to be given for patients to register dissent.**

The poster was updated in line with the above and accepted by CAG.

4. **Further details on the dissent mechanisms in place need to be provided:**

    a. **Clarify that the National Data Opt-Out will be applied by NHS Digital before they carry out the data linkage and that other objections will be registered as they are made by individual patients.**

b. **Clarify if the local opt-out mechanism will include the ability to opt-out of the transfer of data from the University of Westminster to the University of Southampton.**

The applicants stated that NHS Digital will apply the national data opt before linkage and any local opt out will be respected, be it trhough University of Southampton or University of Westminster. However, once the dataset is deidentified any future opt outs will not be able to be respected as the data will not be able to be reidentified.

The CAG accepted this response.

5. **Clarify whether the University of Westminster will retain any of the DietCompLfy study data or whether all study data will now be held at the University of Southampton.**

The applicants confirmed that all data will be held at the University of Southampton, and no data will be returned to the University of Westminster.

The CAG were content with this response.

6. **Further details need to be provided on the de-identification process to be carried out on the paper records transferred. Assurance needs to be given that the process of de-identification for both electronic and paper records is robust enough to ensure that an exit point of support is achieved.**

The applicants provided a document detailing risk of disclosure process at University of Southampton for ABC Discover. Once the patient consent forms are separated from the questionnaires and diaries, these will be destroyed as per local processes.

The CAG accepted this response.

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

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. Confirmed 04 March 2021

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 below titled 'security assurance requirements' for further information.

   Confirmed: The NHS Digital 2019/20 DSPT reviews for the University of Southampton Clinical Trials Unit, University College London – School of Life and Medical Sciences,

and NHS Digital were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 19 March 2021).

f. 20/CAG/0151 - NHS Digital and BAD: Dermatology Intervention Service and Clinical Registries

Name	Capacity
Ms Sophie Brannan	CAG member
Dr Patrick Coyle	CAG vice-chair
Dr Harvey Marcovitch	CAG member
Ms Diana Robbins	CAG member
Mr Marc Taylor	CAG member
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from the British Association of Dermatologists set out the purpose of creating a national audit of the NICE Service Guidance on the organisation and delivery of dermatology healthcare services, which will provide the national NHS dermatology service with clinical outcomes for benchmarking by individual consultants, their trusts, Clinical Commissioning Groups and patients in England.

The dermatology specialty is largely outpatient-based, and diagnostic data is not routinely collected to identify patients’ skin disease and co-morbidities. Trusts also have historically under recorded outpatient procedural data. This has made it difficult to undertake qualitative and quantitative data analysis to audit and benchmark services. The applicants will create a national audit intended to address these deficiencies and support quality improvement activities, local clinical audit processes and to deliver improved, measurable patient care. The data will also be used to help dermatology departments to achieve some of the areas for improvement identified in the It Right First Time (GIRFT) programme.

The applicants seek support to allow the disclose of confidential patient information from participating NHS trusts to NHS Digital. The confidential patient information will be entered into the NHS Digital Clinical Audit Platform (CAP) system by staff at participating NHS trusts in England. An extract of identifiable and sensitive data will be taken for statistical analysis by NHS Digital, and reports created of de-identified aggregate data. Reports with identifiable data will be made available within CAP for individual organisations to access their own

results for local audit. There will be no linkage to other datasets. The data collection is prospective and will be undertaken on a yearly basis to provide the comparative analysis needed to inform on patient demographics, skin disease rates and efficacy of treatments.

A recommendation for class 1, 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	All (child and adult) dermatology patients receiving phototherapy treatment and/or cutaneous allergy testing, seen in outpatient secondary care departments and tertiary dermatology centres in NHS trusts in England. Approximately 600,000 attendances for dermatological treatment occurred in 2019.
Data sources	Clinical data for eligible patients at participating trusts, input into the NHS Digital Clinical Audit Platform (CAP) system.
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode – district level 4. Sex 5. Ethnicity 6. Consultant GMC code
Identifiers required for analysis purposes	1. NHS Number 2. Date of birth 3. Postcode – district level 4. Sex 5. Ethnicity

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. **Please confirm that staff from the clinical care team in all participating trusts will undertake the input of confidential patient information, or whether support under s251 was also needed for those outside of the direct care team to input confidential patient information into the database.**

The applicants confirmed that staff from the clinical care team in all participating trusts will undertake the input of confidential patient information, and no support was needed for this element.

No further comments were raised by the CAG.

2. **Provide further justification needs to be given on why consent cannot be sought at the time of providing patients with the information sheet.**

Following further clarification the applicants stated that, to conduct a proper audit of individual services, local and regional, data is needed from all patients for each of the clinical interventions for the registry. Further appointments are only 15 minutes long and there is not time to undertake proper consent procedure. Adding this in would increase appointment times significantly and is not feasible.

The CAG were content with this response.

3. **Clarify if the British Association of Dermatologists only are the data controllers for this application, with NHS Digital and the participating trusts as data processors.**

The applicants confirmed that the British Association of Dermatologists only are the data controllers, with the CAG content with this response.

4. **A local patient notification and dissent mechanism needs to be created and the materials provided to the CAG.**

Following further clarification the applicants updated the patient notification to add a local opt out mechanism; either by informing their treating clinician or contacting NHS Digital (separate to the national data opt out).

The CAG were content with this response.

5. **Further details need to be provided on the patient and public involvement conducted, including clarifying the involvement of lay representation.**

Following further clarification, the applicants provided a letter of support from the Dermatology Council for England, which was supportive on the use of identifiable data without consent for the purposes in the application. Further the applicants stated their intention to have ongoing annual meetings with patient representatives.

The CAG were content with the response, though requested a report on the further patient and public involvement intended at the first annual review.

6. **Clarify whether the identifiable dataset will be held within participating trusts only for 5 years after the close of the audit or whether confidential patient information would also be held by NHS Digital.**

The applicants stated that, whilst NHS Digital will only hold the data for five years after the close of the audit, participating trusts will continue to be able to access the data as it is patient information. The CAG were content with this response.

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 Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. At the first annual review, provide a report on further patient and public involvement undertaken by the applicants.

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 below titled 'security assurance requirements' for further information. Confirmed.

   The NHS Digital 19/20 DSPT review for NHS Digital was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (21 June 2021)

g. 21/CAG/0063 - The Impact of introducing real time feedback on ventilation rate and volume by ambulance clinicians in out of hospital cardiac arrest

Name	Capacity
Dr Patrick Coyle	CAG vice-chair
Dr Sandra Duggan	CAG member
Professor Barry Evans	CAG member
Dr Liliane Field	CAG member
Professor Lorna Fraser	CAG member
Dr Katie Harron	CAG member
Mr Tony Kane	CAG member

Dr Simon Kolstoe	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Mr Marc Taylor	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the North East Ambulance Service NHS Foundation Trust set out the purpose of medical research that seeks to determine whether introducing real time ventilation feedback improves clinician compliance with recommended rate and volume of ventilation in clinical practice during out of hospital cardiac arrest.

Cardiac arrest is a life-threatening emergency and occurs when the heart suddenly stops beating. When the heart stops beating it cannot pump blood to the brain, lungs and other organs. When a cardiac arrest occurs in the community, outside of a hospital setting, it is called an out of hospital cardiac arrest (OHCA). When attending a patient suffering an OCHA, paramedics are required to deliver chest compressions and to assist breathing, by inserting a tube into patients mouths and squeezing a bag inflated with oxygen. It is important that the right amount of oxygen is delivered. Recommendations exist on how much oxygen should be delivered; however many paramedics administer too much or too little. Until recently, there has been no method to measure how much oxygen patients receive. A new feedback device has been developed. This device attaches to the tube which is inserted into the patient's mouth. The other end of the device is connected to the defibrillator screen used by paramedics. When a paramedic squeezes the bag to deliver oxygen, the amount of oxygen delivered will appear on screen. Paramedics can then respond to any under or over delivery of oxygen. A five second counter is also included, which tells the paramedics when to squeeze the bag.

The applicants plan to undertake a clinical trial to determine whether use of this device improves paramedic compliance with ventilation recommendations during OCHA and if this improves patient outcomes. The trial will take place at three ambulance stations, Blucher, Redcar and Middlesbrough, which are all part of the North East Ambulance Service NHS Foundation Trust. Patients will not be randomised, instead the treating stations will be randomised. Clinicians based at each ambulance station will form a cluster. Initially no cluster will be exposed to real time ventilation feedback and all will be control clusters. All control clusters will use the real time ventilation feedback device but will receive no feedback. Each month one cluster will be randomised to 'switch on' the device and will move from control to intervention, until all clusters are exposed to real time ventilation

feedback and are using the feedback during OHCA. Following all clinical assessments and confirmation of OHCA, the paramedic will confirm the patient meets the eligibility criteria. If the patient is eligible the paramedic will enrol the patient in the study and use the ventilation feedback device when providing ventilations. At the end of the study there will be a period when all clusters are exposed. Data collection will continue throughout the study, so that each cluster contributes observations under both control and intervention observation periods. The applicants explained that all patients will receive full standard care, however those treated while the feedback device is 'turned on' will receive additional care, in the form of the device being used. It is very likely that patients will be unconscious when receiving treatment and prior consent cannot be sought due to the emergency nature of the situation.

When a patient has been enrolled in the study and the resuscitation has been completed, the study paramedic will send a unique incident number via text to a secure study mobile telephone held by the research paramedic. All recruited patients will be allocated a unique study identification number by the research paramedic, who will access the patients' electronic patient records to determine if they have been conveyed to the emergency department. Patients who have been conveyed to the emergency department will be tracked remotely by the research team. The research paramedics will screen NEAS OHCA audit reports for missed recruitment opportunities and to check for patient enrolment that has not been reported to the research team. Patients who are conveyed to hospital will be followed-up remotely by the research team. Patients who have died during the index visit will have their study data collected and input into the study database, and then their data will be anonymised. Patients who have been declared deceased on scene and have not been conveyed will remain in the study and the research paramedic will collect their study data from the electronic patient record and enter it onto the study database. This data will be anonymised immediately. Support is needed for the processing of confidential patient information for deceased patients.

A recommendation for class 1, 4, 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	All patients aged 18 years and over who are treated for out of hospital cardiac arrest by North East Ambulance Service NHS Foundation Trust. The target for recruitment is 48 patients. The applicant noted that recruitment will take place over a four-month period and that recruitment will continue if the target is reached before the conclusion of the study period.

Data sources	1. Electronic ambulance care records at North East Ambulance Service NHS Foundation Trust 2. Electronic patient records at South Tees Hospitals NHS Foundation Trust, Newcastle Hospitals NHS Foundation Trust and Northumbria Healthcare NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Date of death 4. Postcode – district level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – district level 4. Gender

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. **Revisions to the patient notification materials are required, as below;**

    a. **The Patient Information Sheet is to be revised to be less technical and suitable for a lay audience, although noting that this is more an issue for the REC.**

The applicant made changes to the patient information sheet, and provided additional new documents in line with REC suggestions. CAG members were content the documents provided were enough to now recommend support, although noting that this is more in the remit of the REC and the CAG trust that the applicant will make any necessary improvements to the notifications as per REC advice.

    b. **A poster is to be displayed in the A&E departments of participating trusts, alerting patients that the research is taking place.**

A poster has been provided, and the CAG members were content with this document.

    c. **A postal address is to be provided on all patient notification materials; the website notification, Information Leaflet and poster.**

A postal address has now been included and the Sub-Committee were content with this response.

d. All patient notification materials need to make it clear that this is a research project.

This has now been clarified in the materials, and the Sub-Committee were content with this response.

2. Confirm that the opt-out will be applied as soon as the researchers became aware that the patient had registered an opt-out and that more identifiers than address alone would be used to apply the opt-out.

The applicant has confirmed this will be applied as soon as the researchers are aware one has been registered. Identifiers used are confirmed as name, address including postcode, date of birth and NHS number to screen the patient against the opt out. The Members were content with this response.

3. Please confirm that sufficient numbers of patients were involved in the patient and public involvement and engagement undertaken.

The applicant confirmed that the cardiac rehab group involved 2 patient and public involvement sessions involving approximately 25 participants at each session. Attendees at the group were diverse people who had suffered a cardiac event (myocardial infarction, cardiac arrest) and their relatives and varied in age. The research design service panel comprised 6 participants and of varying ages. The Sub-Committee were content with this response.

4. Confirm that the National Data Opt-Out will be applied.

The applicant has confirmed that the national data opt out will be applied, and the Members were content with this.

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

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. Confirmed 07 June 2021

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 below titled 'security assurance requirements' for further information.

   Confirmed:

   The NHS Digital 19/20 DSPT review for Newcastle Hospitals NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 06 May 2021)

   The NHS Digital 19/20 DSPT reviews for South Tees Hospitals NHS Foundation Trust and Northumbria Healthcare NHS Foundation Trust were confirmed as 'Standards Met' (by email to the CAG inbox on 28 May 2021)

   The NHS Digital 19/20 DSPT review for North East Ambulance Service NHS Foundation Trust was confirmed as 'Standards Met' (by email to the CAG inbox on 22 June 2021)

h. 21/CAG/0062 - Barts Haemato-Oncology Research Tissue Bank (HOTB)

Name	Capacity
Mr David Evans	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Barts Cancer Institute, Queen Mary University of London set out the purpose of medical research that aims to provide support for Barts Haemato-Oncology Research Tissue Bank (HOTB) team staff, who are not members of the direct care team to identify and screen patients attending Haemato-Oncology clinics and wards at Barts Health for eligibility, in order to subsequently seek their consent into the Barts HOTB. The aim of the HOTB is to recruit patients and healthy volunteers, to collect, store and share high quality tissue and bodily fluids and associated clinical data for translational research into haematological malignancies; however all other processes of the HOTB do not require Regulation 5 support, as all participants are consented. The current HOTB model is for the direct care team to identify and consent eligible patients, but the applicants have identified that this model is not practicable as the process is very inefficient. The direct care team is not able to spend time identifying and introducing the patients to the HOTB team during very busy clinic hours and consequently the number of identified patients is currently very low.

Haematological malignancies comprise a variety of different tumour types affecting the bone marrow, blood and lymph glands. Collectively, they remain the third biggest cause of cancer deaths, and the incidence and age of patients with haematological malignancies are rising. The treatments available are frequently toxic and often cannot be given to older or unfit patients. There is therefore a continued need to better understand these malignancies, and the HOTB will help a number of local, national and international researchers to investigate the causes of haematological cancers, in order to improve diagnosis, early detection, preventative strategies and treatment for haematological cancer patients in the future.

Members of the HOTB team, who are not members of the direct care team, will use Barts Health patient records such as Cerner Millennium Powerchart, NHS.net calendars and EPR to identify and screen patients that may be appropriate to approach for consent. Any patient who has opted out via the national data opt out will be removed from the screening process.

This process is still in development but will be implemented by September 2021. All patients that may be eligible for HOTB (with a suspected or diagnosed haematopoietic malignancy) will be recorded on the shared calendar of the BCI (Barts Cancer Institute) Tissue Bank shared NHS.net email address (within the Barts health NHS Trusts servers). In order to undertake screening, HOTB staff will view confidential patient information (Full name, NHS Number, Hospital number, Date of birth). HOTB staff will record if a patient is eligible or not on a shared calendar of an NHS.net email address on the Barts NHS Trust servers, using the stated items of confidential patient information. This will show whether a patient needs to be approached to request consent.

The HOTB team member will use the shared calendar entries to approach the direct care team and ask whether it is appropriate to approach the identified patient for consent. Providing the direct care team are happy that it is appropriate to consent the patient for research purposes the HOTB team member will approach potential patients in order to gain consent. Patient consent or dissent to the Tissue Bank will continue to be recorded on the patient's record on Millennium Powerchart to prevent a dissented patient being inadvertently re-approached. However, the identifiable details of any patient that dissents will not be recorded or stored in the HOTB systems. Any hard copies of screening will be destroyed through confidential waste or shredded, although the applicant has confirmed there should not be any paper copies.

A recommendation for class 1, 3, 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	All patients attending Haemato-Oncology clinics and wards at Barts Health NHS Trust with a suspected or diagnosed haematological malignancy Approximately 160 patients a week will be screened, to identify approximately 20 eligible patients.
Data sources	Barts Health NHS trust: Electronic Patients Record (EPR) and Care Record Service (CRS)/Millennium Powerchart, WinPath, CyberLab and Varian prescribing system. This includes lists of patients attending day-unit, clinics or wards, which could be provided by direct care team, as well as the physical procedure diary on the day-unit, and NHS.net calendars.

Identifiers required for identification of cohort	1. Full name 2. NHS Number 3. Hospital number 4. Date of birth
Identifiers required for analysis purposes	1. N/A – undertaken with consent

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. **Please provide the favourable opinion from the REC when available (standard condition of support, see below).**

The applicant received REC favourable opinion on 11th June and provided this to CAG on the same day. The CAG were content with this response.

2. **The text notification for the clinic appointment letter, and website, needs to be provided in line with the advice provided in this letter.**

The applicant provided the text to be used in the clinical appointment letter and the website, and the CAG were content with this response.

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

The following sets out the specific conditions of support.

1. Support provided for 5 years in line with REC favourable opinion. A duration amendment will be required at this time to extend support.

2. Favourable opinion from a Research Ethics Committee. Confirmed 11 June 2021.

3. 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. Confirmed:

The NHS Digital 19/20 DSPT review for Barts NHS Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 25 May 2021)

i. 21/CAG/0056 - A randomized, controlled trial to assess the clinical utility of a multi-cancer early detection (MCED) test for population screening in the United Kingdom (UK) when added to standard of care

Name	Capacity
Dr Martin Andrew	CAG Expert Member
Dr William Bernal	CAG Alternative Vice-Chair
Dr Malcolm Booth	CAG Expert Member
Ms Sophie Brannan	CAG Lay Member
Mr David Evans	CAG Expert Member
Dr Tony Calland MBE	CAG Chair
Mr. Myer Glickman	CAG Expert Member
Ms Diana Robbins	CAG Lay Member
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Grail Bio UK Ltd and Kings College London (KCL) set out the purpose of a randomised controlled trial (RCT) that aims to understand whether the Galleri™ test (a Multi-cancer early detection (MCED) test) is a better way of detecting cancer early than the existing NHS pathway in people who do not have any symptoms of cancer.

The Galleri™ test is a new blood test that can detect signs of many different types of cancer in a single blood sample. If the Galleri™ test can find these signs earlier than other tests and before people have symptoms of cancer, it may mean cancer treatments that are less serious, less invasive and more successful can be utilised. NHS England has set an

ambition to achieve a significant shift in the proportion of cancers diagnosed at an early stage by 2028. An intent of this study is to understand if the Galleri™ test can contribute to this aim. The RCT is consented and outside the scope for support.

Regulation 5 support is required solely for the activity of identifying potential patients by the processor(s) of this activity. This will be undertaken by NHS Digital (under the brand of NHS DigiTrials https://digital.nhs.uk/services/nhs-digitrials) and a sub-contracted third party mail-out company (APS) to send out invitation letters to seek consent. Potential participants will be identified via three methods, however Regulation 5 support has been requested for NHS Digital and APS, as a sub-processor, to undertake the invitation approach only.

Identification of the cohort will be undertaken by NHS Digital using the Personal Demographic Service (PDS) dataset to extract a cohort of eligible patients, and link to the National Cancer Registration and Analysis Service (NCRAS) to exclude certain cancer diagnoses. NHS Digital will apply the national data opt out, and PHE-specific opt out for the NCRAS data. Date of death will be checked in order to exclude any participants who have died. A pseudonymised invitation code for each individual is added to the dataset by the NHS Digital team.

NHS Digital will disclose name, full postal address, month and year of birth, and invitation code to APS in order to send the invitation letters to identified participants. Invitation letters will be sent out once only. Invitees will be invited to contact a study contact centre via a study website or phone if they are interested in participating, after which consent will be provided if participating. The central study team at KCL and Grail Bio UK Ltd will only learn about the invitee when they contact the central study team to express interest in participating.

The recruitment process is expected to take 10-12 months after June 2021, but could take up to 18 months, and potential participants will be identified in monthly data extracts by NHS Digital. Identifying information is deleted by APS two weeks after each mailout.

A recommendation for class 3, 4 and 6 support was requested to cover access to the relevant unconsented activities by NHS Digital and APS 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	Approximately 2.8 Million people in the general population, not currently diagnosed with cancer (or within the last three years) aged 50-77 to be contacted by letter in order to obtain consent from 140,000 participants

Data sources	1. The Personal Demographic Service (PDS) dataset (held by NHS Digital) 2. The National Cancer Registration and Analysis Service (NCRAS). (PHE is the controller for NCRAS but data is held within NHS Digital currently for other COVID-19 purposes. PHE have provided permission for NHS Digital to use NCRAS data for this purpose if support is in place)
Identifiers required for identification and invitation purposes	Data items required for identification of cohort by NHS Digital: 1. Age 2. Sex 3. Postcode 4. Ethnicity 5. Date of death 6. History of invasive cancer diagnosis or treatment within the three years prior to the query 7. Current investigation for suspected cancer via the two-week wait pathway 8. Receiving hospice and end of life care through a Gold Standards Framework (GSF) Centre In order to send out patient letters the following identifiers are disclosed to APS: 1. Name 2. Address including full postcode 3. Month and year of birth (as mentioned on letter) 4. Invitation code (as mentioned on letter)
Additional information	NHS DigiTrials will extract lists of eligible participants approximately monthly for up to 18 months. However, if recruitment is slow or there are key groups under-represented then the number of extracts may be increased to weekly.
Areas out of scope	The applicant has stated that the following are outside the scope of this application and do not require support under

	Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002: 1. Identification of participants via query of GP practice records and invitation by GP. 2. Participant self-identification via an interested individual who presents after learning about the study from family member or friends, or from seeing the study recruiting in their area. 3. 'Phase 2' screening using the GP dataset held by NHS Digital is not yet ready to be supported and an amendment will be submitted in due course. 4. All flows of data after the time point participants consent to participate.

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. **Please explain why NHS Digital is considered a processor for this application in the context of the points raised in the letter. This should also include clarity on the decision-making and sign-off for relevant activities by KCL and GRAIL in their capacity of joint controllers, and how NHS Digital decision-making process fits in with its processor role.**

The applicants have confirmed that NHS Digital are not considered a joint data controller for this application, and assured CAG that Grail Bio UK Ltd will be responsible for providing the final, approved versions of all patient facing documents for use in the trial. The documents will be approved internally at Grail Bio UK Ltd and by REC. The Members were content with this response.

2. **Please confirm if support is required for the flow of NHS number and date of invitation letter sent from APS to NHS Digital.**

Applicants confirmed support is not required for this; NHS Digital will keep a record of each batch for six months which would contain the NHS number, cohort ID and date of the mailing, to prevent any further communication being sent to these Individuals as per the protocol. Cohort ID is not specific to individuals and is not confidential patient information. This is further clarified in an email sent 2 June 2021. The Committee were content with this response.

3. **Please provide a credible and appropriately detailed plan for a communications strategy prior to the breach in confidentiality occurring, describing the specific proposals for the geographical areas concerned and a rough timetable to achieve the proposed plan.**

The applicants have provided a document; "NHS-Galleri Trial pre-invitation communications plan", which provides details of the communications strategy. Grail Bio UK Ltd has commissioned a strategic communications agency, Claremont, with expertise in trial 'pre-breach' communications. The proposal sets out approaches to the geographical areas concerned, with an indicative timetable., and the applcants are also working closely with all eight cancer alliances to help achieve the proposed plan. The CAG were content with this response.

4. **Please provide an updated version of the website text to the CAG. Improvements made should be based on the suggestions below:**

    a) **The explanation of the function of CAG should be corrected.**
    b) **Incorrect statements regarding data flow should be corrected.**
    c) **Language should be amended to be more accessible and headers should be entitled more clearly.**
    d) **Opt out contact details should be provided.**

The applicants have provided an updated version of the website text to the CAG, in line with the suggestions above. The CAG were content with this response.

5. **Please provide an updated version of the invitation letter to the CAG. Improvements made should be based on the suggestions below:**

    a) **Consider an NHS logo, KCL logo and Grail logo on the letter, or provide stronger justification if this approach is not considered appropriate.**
    b) **Ensure the connection between NHS England and the study is clear, or consider an alternate signatory.**
    c) **Remove NHS number from the letter.**
    d) **Remove GP details from the invitation letter, or provide a stronger justification as to why an alternative is not possible.**
    e) **Consider if month and year of birth or age in years should be used on the invitation letter.**
    f) **Ensure the text is clear regarding that person being invited to take part in a research trial of a cancer test.**
    g) **Ensure the text is clear regarding how the participant has been contacted to avoid any mistaken perceptions.**
    h) **The role of CAG and the legal basis of the participant identification and invitation process should be clearly explained.**
    i) **The letter should explain what happens if the participant does not take part.**

The applicants have provided an updated invitation letter to the CAG, in line with the suggestions above. The CAG were content with this response.

6. **Please provide an updated version of the participant information sheet to the CAG. Improvements made should be based on the suggestions below:**

a) **Consider a layered approach.**
b) **Remove the statement *'you are receiving this information sheet because you have contacted us about taking part'*, and ensure clarity and consistency throughout.**
c) **Ensure the data sources are clearly explained.**
d) **Ensure the pseudonymous data flow to the USA is clearly explained.**

The applicants have confirmed that they will be undertaking a layered approach to patient notification, and that a participant leaflet had been developed to be sent with the invitation letter but had not been sent to CAG for review. This has now been provided. Therefore the statement 'you are receiving this information sheet because you have contacted us about taking part' has been left in the information sheet, as this is only provided to patients who have requested further information about the trial. The data sources have now been clearly explained and the flow of data to the USA is clearly explained. The CAG Members were broadly content with this document, but noted that in the invitation letter it is stated that the NHS Digital search is electronic, but in the participant information sheet it reverts to the original text which implies that a person has looked at their medical records. Both documents need to emphasise that the search to identify suitable recruits was electronic and not done by human viewing of the record, and the Members requested this document to be updated before support was provided. The Applicant updated this text, and provided version 3 of this document, and the CAG were content with this updated response.

7. **Please undertake further patient and public involvement with a larger group of people.**
   a) **This should specifically discuss this use of confidential patient information without consent, and detailed feedback of the events should be provided to the CAG.**
   b) **A patient and public involvement group should review the entire suite of intended communications.**
   c) **Please consider undertaking patient and public involvement with cancer charities, and in the geographical areas where the invitation letters will be targeted.**

The applicants have confirmed that patient and public involvement work undertaken by Claremont between January and March 2021 had been left out of the application, which involved over 50 participants. In addition, further work has been undertaken following CAG feedback. Details are within the response to CAG document provided, and the use of confidential patient information without consent appears to have been discussed with participants. The patient communication strategy has also been reviewed by patients and public involvement representatives, and work has been undertaken with cancer alliances. The CAG were content with this response.

8. **Please confirm that APS will delete all identifying information including NHS number and GP details within two weeks of sending the invitation letters.**

The applicant confirmed that NHS number and GP details have both been removed from the invitation letter. APS will delete the participant name and address within two weeks of sending the invitation letters. The CAG were content with this response.

9. **Please consider whether support may be required for a larger cohort of individuals to be screened and posted an invitation letter.**

The applicant agreed to request support for 2.8 million individuals to be screened and contacted, however, they will only send the minimum amount of letters required if recruitment is better than expected. The CAG were content with this response.

10. **Please provide the Favourable Opinion from the REC when this becomes available**

The applicant provided this after it was issued on 8th June 2021, and this meets the standard condition of support.

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

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. Confirmed 08 June 2021

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 below titled 'security assurance requirements' for further information. Confirmed:

The NHS Digital 19/20 DSPT review for APS (Allied Publicity Services (Manchester) Limited and the 19/20 DSPT equivalent for NHS Digital were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20 April 2021).

NCRAS data is controlled by PHE, however NHS Digital currently hold this and therefore this data is subject to NHS Digital's governance.

2. New Amendments

a. 21/CAG/0017 – Outcomes of Patients who survived Treatment on an Intensive Care unit for COVID-19 in England and Wales: a retrospective cohort study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Laura Gordon	HRA Confidentiality Advisory Group Assistant

Context

Amendment request

This application gained support to link a cohort of patients from the existing Case Mix Programme (CMP) dataset held by ICNARC with a number of datasets, including those held by NHS Digital.

This amendment seeks explicit support to link the cohort of patients with the Maternity Services Data Set (MSDS) product via NHS Digital.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no issues with the amendment.

Confidentiality Advisory Group advice 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

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:

   Confirmed: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for the following organisations have been assessed as 'standards met' by NHS Digital;

- University of Oxford
- ICNARC 8HN44
- NHS Digital
- NICOR (Barts Health NHS Trust)
- SSNAP King's College London - Sentinel Stroke National Audit Programme EE133874-SSNAP
- UKRR (The Renal association) 8HQ50
- A CPiP assessment is in place for NWIS.

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed non substantial 13 May 2021.

b. 18/CAG/0002 – Trajectories of diabetes related health measures (from linked lab data) and subsequent health and educational outcomes

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG Vice Chair
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Amendment request

The applicants have existing support for the disclosure of confidential patient information from both the National Diabetes Audit (Adults – England) and National Diabetes Audit (Adults – Wales) (held by NHS Digital) and the National Paediatrics Diabetes Audit (held by the Royal College of Paediatrics and Child Health) to NHS Wales Informatics Services (NWIS). Data is also released from the Higher Education Statistics Agency (HESA) dataset to NWIS; however, this is out of the CAG's remit as it is not confidential patient information.

Currently confidential patient information flows from NHS Digital to Department for Education to create a linkage key. To enable better linkage across all the datasets this amendment requests the use of two further linkage keys

- NHS Digital will create an NHS Digital linkage key (note that this is done within NHS Digital and does not result in any external flows of Confidential Patient Information and send the key to the ONS-SRS

- NHS Digital to send NDPA/NDA identifiers to ONS-DAP to create a 'DAP' linkage key (this key is sent to ONS-SRS but does not include any Confidential Patient Information)

Within ONS-SRS the DfE, NHSD and DAP linkage keys are combined. The purpose of using the three keys is that it will enable better linkage between the health and non-health datasets.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair's Action. This was considered by the chair and vice chair who agreed that the amendment would enable improved linkage and were supportive of the amendment

Confidentiality Advisory Group advice 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

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:

2. Confirmed: The NHS Digital 19/20 DSPT review for NHS Digital was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 June 2021)

3. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed as not necessary by the REC.

c. 17/CAG/0130 – Colonoscopic surveillance for familial risk of colorectal cancer

Name	Capacity
Caroline Watchurst	Confidentiality Advisor

Context

Amendment request

This non-research application from London North West Healthcare NHS Trust aims to audit and monitor care provided to individuals at increased familial risk of colorectal cancer and develop evidence-based guidelines on the management of familial risk for the NHS. The applicant has support to obtain outcome and mortality data from NHS Digital regarding over 3000 retrospective patients (prior to support provided 8 September 2017) who are undergoing colonoscopic surveillance for an increased familial risk of colorectal cancer at The Family Cancer Clinic at St Mark's Hospital. Pseudonymised data was then disclosed to Queen Mary College, University of London (QMUL) in order for the statistician to undertake analysis.

This amendment seeks support for a change in data processor from Queen Mary University of London (QMUL) to Kings College London (KCL), as the statistician has moved institutions. Although the applicant has previously described this data flow as pseudonymous, it has been clarified that this data flow contains date of birth and date of death. Therefore Kings College London do receive identifiable information, and support is in place for this data flow.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries with this amendment request.

Confidentiality Advisory Group advice 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 Secretary of State for Health and Social Care.

Specific conditions of support

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:

   Confirmed:

   The NHS Digital **2019/20** DSPT review for **King's College London - Cancer Epidemiology and Population Health** and the equivalent for **NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 08 January 2021)

   The NHS Digital **2019/20** DSPT review for **London North West Healthcare NHS Trust** was confirmed as 'Standards Met' by email to the CAG inbox on 24 June 2021.

d. ECC 7-05(g)/2011 – TARN (Trauma Audit and Research Network)

Name	Capacity
Dr Tony Calland	CAG Chair
Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The Trauma Audit and Research Network (TARN) have existing support to retain patient NHS numbers and dates of birth to support specific activities as a national clinical audit in England and Wales. The specific activities that require these identifiers include supporting the flow of Best Practice Tariff, to assist data completeness across hospitals, and elements of outcome prediction modelling that require data linkage with ONS to obtain true 30 day patient outcomes.

NHS Wales have launched a Major Trauma Network (MTN) in South Wales. The MTN will consist of a Major Trauma Centres (MTC) which will be based in the University Hospital of Wales (UHW) alongside Trauma Units (TU) within each of the six health boards in South Wales. The network went live in September 2020. The Logistics and Operations Management section, based in Cardiff University, has agreed to carry out a service evaluation focussing on patient flow pathways and forecasting in conjunction with NHS South Wales Major Trauma Network.

Anonymised patient related datasets to allow the above analysis are available via the Secure Anonymised Information Linkage (SAIL) databank hosted by Swansea University in partnership with NHS Wales Informatics Service and TARN, which is separately hosted. Access to confidential patient information is required in order to link the separate datasets between these two organisations. In this amendment TARN are seeking to extend their current support to cover this new data flow to NWIS to support this service evaluation project.

Confidential patient information will be disclosed from TARN to SAIL via the NHS Wales Informatics Service (NWIS), which acts as their 'Trusted Third Party (TTP) for anonymisation and encryption. The data required to perform this linkage is NHS Number, DOB and gender. NWIS will replace the commonly-recognised identifiable items (including name, address and date of birth) for each person with an encrypted code and sends this, along with minimal information (on gender, area of residence and week of birth) to SAIL.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair of the Confidentiality Advisory Group who was supportive of the amendment.

Confidentiality Advisory Group advice 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

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:

Confirmed: The NHS Digital 2019/20 DSPT review for Trauma Audit and Research Network was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 07 May 2021)

e. 18/CAG/0166 – National Clinical Audit for Specialist Rehabilitation following major Injury (NCASRI) – Transfer of Controllership Arrangements

Name	Capacity
Dr Tony Calland	CAG Chair
Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

In 2018, the applicants were given support to change the data controller for the National Clinical Audit of Specialist Rehabilitation following Major Injury (NCASRI) from HQIP to TARN. This support was given only for the continued holding of the dataset and not for other processing of the dataset.

In this amendment, the applicants are seeking support to allow the NCASRI dataset to be used for further data linkages. Specifically, the applicants seek to undertake the following:

1. A re-run of the 2016-2017 NCASRI data linkage to capture any cases that were submitted to UK Specialist Rehabilitation Outcomes Collaborative (UKROC) after the end of 2017 that may have been missed previously: this data will show existing fields that were in the original NCASRI linked data. NHS numbers for any linked patients will not be shared with UKROC and continue to be only held by TARN in the University of Manchester Data Safe Haven.

2. A new data linkage project (subject to future funding) to capture more recent patients admitted since 2018, using the same data linkage process previously used, but also including the addition of more recent data fields, relating to rehabilitation prescription only. No identifiable data will be passed to UKROC.

The NHS numbers and Dates of Birth will be used for linkage, but will not be included in the linked dataset that is sent to UKROC. This linked dataset will contain pseudonymised data only.

The applicants anticipate that this linkage process will be completed by April 2022. It was noted that the applicants support, granted via an amendment supported on 21 December 2020, to retain the confidential patient information in the NCARSI database was supported until the next annual review only and this ongoing retention will be considered on an annual basis. The due date for the next annual review is 16 November 2021.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair of the Confidentiality Advisory Group who consider the amendment to be low risk and in the public interest.

Confidentiality Advisory Group advice 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

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:

   Confirmed: The NHS Digital 2019/20 DSPT review for Trauma Audit and Research Network, was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 07 May 2021)

f. CR12/2014 – Oxford Vegetarian Study

Name	Capacity
Laura Gordon	Confidentiality Advisory Group Assistant

Context

Amendment request

This application from the University of Oxford set out a cohort study of 11,000 men and women to study the incidence of cancer and causes of death in vegetarians compared to non-vegetarians. It was confirmed that follow up until 2020 was planned.

This amendment requests to continue processing existing data until 31 December 2023 to continue analyses, plus other minor changes to the protocol.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the amendment was in the public interest.

Confidentiality Advisory Group advice 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

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:

   Confirmed: The NHS Digital 19/20 DSPT review for University of Oxford – Medical Sciences Division – Nuffield Department of Population Health was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (Confirmed 02 June 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 13 May 2021

g. 19/CAG/0096 – A randomised pilot study of a pharmacist-led retrospective review of prescribing by general practitioners in training (REVISiT) intervention

Name	Capacity
Laura Gordon	Confidentiality Advisory Group Assistant

Context

Amendment request

This application gained support under the Regulations to legitimise access to confidential patient information on site at GP practices by the Pharmacist undertaking the review of the GP trainee prescribing practices.

This amendment requests an extension to support until October 2022 due to delays encountered by the COVID-19 pandemic

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no issues with the amendment.

Confidentiality Advisory Group advice 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

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:

   Not checked due to the number of research sites involved. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to accessing confidential patient information with support under the Regulations.

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 30 April 2021.

h. 20/CAG/0088 – Antihypertensive Treatment in Elderly Multimorbid Patients: a pilot study

Name	Capacity
Patrick Coyle	CAG Vice Chair
Paul Mills	Confidentiality Advice Service Manager

Context

Amendment request

This application received support for the transfer of patient identifiable information from NHS Digital to the University of Oxford for the study team to invite patients into the ATEMPT study. Patients will consent to the study which acts as an exit strategy for support.

- Following the study team discussing flows with NHS Digital, this amendment requests some changes to the data items and flows that CAG supported. These include:
- NHS number to no longer be shared by NHS Digital
- Identifiable information from NHS Digital (held in a pre-screening database) to only be copied to the ATEMPT study database at the point of consent. Previously this was done at point of registering an interest and this change negates the need to remove information from the ATEMPT database of those who register an interest but do not consent.
- Updated patient information materials to reflect the above changes
- Extension of support until March 2022, in light of COVID-related delays.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair was content to support the request, noting that the primary changes resulted in a reduction in disclosure.

Confidentiality Advisory Group advice 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

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:

   Confirmed: The NHS Digital 19/20 DSPT review for University of Oxford Medical Sciences Division was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (11 May 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 21 May 2021.

i. 18/CAG/0207 – Defining delirium and its impact in Parkinson's Disease (DELIRIUM-PD)

Name	Capacity
Paul Mills	Confidentiality Advice Service Manager

Context

Amendment request

This study from Newcastle University aims to understand the incidence of delirium in Parkinson's disease. Support is currently in place to disclose confidential patient information relating to patients with Parkinson's treated at Newcastle upon Tyne Hospitals Foundation Trust, to the DELERIUM-PD research team, to facilitate the recruitment process.

This amendment is seeking to extend the duration of support under the Regulations until 31 October 2021 for the purposes of screening and recruitment. This is due to study recruitment being temporarily paused due to Covid-19.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no issues.

Confidentiality Advisory Group advice 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

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:

   Confirmed: The NHS Digital 19/20 DSPT review for Newcastle upon Tyne Hospitals NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (26 April 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 13 May 2021.

j. 18/CAG/0180 – LAUNCHES QI: Linking AUdit and National datasets in Congenital HEart Services for Quality Improvement.

Name	Capacity
Paul Mills	Confidentiality Advice Service Manager

Context

Amendment request

This application gained support to link to a number of national datasets for medical research which aims to improve services for congenital heart disease and provide a template for other lifelong conditions.

This amendment requests an extension to support until 30 April 2022 due to delays encountered by the COVID-19 pandemic as well as notifying of changes to the investigator team.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no issues with the request.

Confidentiality Advisory Group advice 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

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:

   Confirmed: The NHS Digital 19/20 DSPT review for University College London - School of Life and Medical Sciences was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 17 May 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed as non-substantial and, as such, REC favourable opinion not necessary.

k. 20/CAG/0027 – Congenital Heart Audit: Measuring Progress In Outcomes Nationally

Name	Capacity
Paul Mills	Confidentiality Advice Service Manager

Context

Amendment request

This application gained support to link data from 130,000 children and adults with congenital heart disease with a number of datasets.

This amendment requests an extension to support until 30 September 2023 due to delays encountered by the COVID-19 pandemic.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no issues with the request.

Confidentiality Advisory Group advice 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

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:

   Confirmed: The NHS Digital 19/20 DSPT reviews for University College London - School of Life and Medical Sciences and NHS Digital were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 June 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed as non-substantial and, as such, REC favourable opinion not necessary.

I. 20/CAG/0054 – SHINE

Name	Capacity
Paul Mills	Confidentiality Advice Service Manager

Context

Amendment request

This application gained support to allow members of the research team, who are not members of the direct care team, to access confidential patient information held in the Electronic Patient Record to identify patients meeting the inclusion criteria and seek their consent. This amendment request seeks to extend the study to South Warwickshire NHS Foundation Trust and Royal Berkshire NHS Foundation Trust.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no issues.

Confidentiality Advisory Group advice 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

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:

   Confirmed: The NHS Digital 19/20 DSPT review for South Warwickshire NHS Foundation Trust and Royal Berkshire NHS Foundation Trust were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (21 May 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 11 June.

m. 19/CAG/0162– Accuracy, impact and cost-effectiveness of prehospital clinical early warning scores for adults with suspected sepsis

Name	Capacity
Dr Tony Calland	CAG Chair
Paul Mills	Confidentiality Advice Service Manager

Context

Amendment request

The applicants have existing support to allow research paramedics access to confidential patient information on site at participating ambulance Trusts to enable the eligible patient cohort to be identified, the onward disclosure to NHS Digital and access to confidential patient information at participating Trusts by research nurses

Following discussions with NHS Digital the applicant seeks to amend the flows of identifiable data once NHS Digital has received identifiers from the ambulance service and linked to the approved datasets.

The applicants now propose that NHS Digital share NHS data together with NHS number to University of Sheffield (CTRU). Once received the University of Sheffield will onward disclose the NHS number (together with study ID) with the relevant participating hospitals to collate data and return pseudonymised data to University of Sheffield.

An updated poster was also provided to reflect these changes.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group who agreed that the proposed changes are in the public interest and provides clarity in flows.

Confidentiality Advisory Group advice 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

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:

Confirmed: The NHS Digital 19/20 DSPT review for University of Sheffield - School of Health and Related Research was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 17 June 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 7 June 2021

3. Annual Review Approvals

CAG 10-02(d)/2015	National Congenital Anomaly and Rare Disease Registration Service
17/CAG/0023	National Bariatric Surgery Registry (NBSR)
ECC 4-02(FT1)2012	Norfolk Arthritis Register (NOAR)
ECC 5-04(e)/2011	SIGGAR1 (Special Interest Group in Gastrointestinal and Abdominal Radiology): CT colonography, colonoscopy or barium enema for the diagnosis of colorectal cancer in older symptomatic patients
18/CAG/0207	Defining delirium and its impact in Parkinson's Disease (DELIRIUM PD)
16/CAG/0134	Follow-up of the Hertfordshire Cohort Study through Hospital Episode Statistics
19/CAG/0194	Identifying models of care to improve outcomes for older people with emergency and urgent care needs
20/CAG/0009	The Cambridge Cohort - Mammography East-Anglia Digital Imaging Archive (CC-MEDIA)
ECC 8-04(c)/2013	Out of Hospital Cardiac Arrest Outcomes (OHCAO)
ECC 5-02(FT4)/2009	Study of Heart and Renal Protection (SHARP)
17/CAG/0054	Life and Bladder Cancer: The Yorkshire Cancer Research Bladder Cancer Patient Reported Outcomes Survey (PROMs)
ECC 3-04(k)/2011	UK Surveillance of Primary Congenital Hypothyroidism in Children
18/CAG/0056	Retinoblastoma gene mutations and risk of second primary tumours
15/CAG/0115	UKCTOCS UK Collaborative Trial of Ovarian Cancer Screening
19/CAG/0209	Advanced cardiovascular risk prediction in the acute care setting
14/CAG/1032	Association between IQ and self harm
15/CAG/0175	Early life causes of depression and anxiety
15/CAG/0176	Predictors, prevalence and impact of chlamydia
19/CAG/0096	A randomised pilot study of a pharmacist-led retrospective review of prescribing by general practitioners in training (REVISiT study)
17/CAG/0130	Colonoscopic surveillance for familial risk of colorectal cancer

Signed – Chair	**Date**
Agreed via correspondence	22 July 2021
Signed – Confidentiality Advice Team	Date
	22 July 2021