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

May 2021

1. New Applications

a. 21/CAG/0032 - Non-statutory Medical Examiner System – second phase

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Malcolm Booth	CAG expert member
Mr Andrew Melville	CAG lay member
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from NHS England and NHS Improvement set out the purpose of the implementation of the National Medical Examiner system in England.

The National Medical Examiner system forms part of the NHS Patient Safety Strategy in England and is an important component of improving patient safety. Medical examiners provide independent scrutiny of causes of death and the care before death, and to facilitate feedback from the bereaved. The Government's proposals for medical examiners, and for a new rigorous, unified system of death certification for both burials and cremations in England

and Wales, is part of the response to several independent inquiries into deaths, including the Shipman Inquiry, the Francis Inquiry into Mid Staffordshire, the Morecambe Bay Inquiry and the Gosport Inquiry. This application has been made to implement the system in England only. Primary legislation is expected to put the system on a statutory footing from April 2022. The applicants seek to establish a legal basis for the disclosures of confidential patient information made to medical examiners employed by host trusts before the statutory system becomes operational.

The programme is comprised of two phases. The first phase, which involved setting up medical examiner offices within NHS trusts and NHS foundation trusts, is already underway. Medical examiners are senior doctors employed by Host Trusts, to provide independent scrutiny of non-coronial deaths, and are operating in larger NHS trusts and NHS foundation trusts across England ("Host Trusts"), reviewing deaths that occur in their organisation. Medical examiners and medical examiner officers currently access Trust patient records undertake this review.

This application concerns the next phase of the programme, where the medical examiner offices will provide independent scrutiny of non-coronial deaths which occur in settings outside the Host Trust (for example, at home or in the care of other health providers, such as hospices and private hospitals). This will require medical examiners to access the records of deceased individuals held outside Host Trusts by different healthcare providers. The wide range of patient record systems utilised by providers means that local arrangements to enable independent scrutiny to take place will vary. Medical examiner scrutiny will take place in the brief window before the death must be registered (5 days) and has three elements; discussion with the doctor completing the medical certificates of cause of death; giving the bereaved an opportunity to ask questions about the causes of death and raise any concerns; and a proportionate review of the patient record.

The medical examiners will require access to confidential patient information for deceased patients who were cared for by other providers. These healthcare providers, such as GPs, independent healthcare providers, and NHS Trusts and NHS foundation trusts which do not host a medical examiner office, will share medical records of deceased patients (with medical examiners and medical examiner officers, or provide equivalent access to review such records, for example through electronic patient record systems. Medical examiners will carry out a proportionate review of the records of these deceased patients, as part of their independent scrutiny. They will also contact the next of kin identified in the patient record to ask if they have questions about the causes of death or concerns about care before death. After the medical examiner has completed their work, the patient record will remain with or be returned to the original healthcare provider. Medical examiner offices will retain records of their scrutiny, including patient identifiable data, and these records will be maintained in line with the information governance and data security policies of their NHS Trust or NHS foundation trust. Where medical examiners identify points for learning or improvement, medical examiners will indicate these for further investigation through established clinical governance and quality processes, such as mortality reviews.

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

Confidential patient information requested

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

Cohort	All deaths which occur in England that are not referred to a coroner and occur outside the host Trust of a medical examiner (approximately 240,000 per annum)
Data sources	1. Electronic and paper records held at healthcare providers outside host Trusts of the medical examiner. For example, GPs, independent healthcare providers (e.g. hospices and private hospitals), and NHS Trusts and NHS foundation trusts which do not host a medical examiner office
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Date of death 4. Place of death 5. NHS number 6. Contact details of next of kin, likely to include name and telephone number, and in some cases, address and/or email address
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. Date of death 4. Place of death 5. NHS number 6. Contact details of next of kin, likely to include name and telephone number, and in some cases, address and/or email address

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. **Provide rationale as to why phase one of this project does not require Regulation 5 support, but phase two does. This should include clarification on the legal basis relied upon for phase one and confirmation whether, following further discussions, phase two requires Regulation 5 support.**

Subsequent to the provisional outcome the applicants discussed the application and appropriate legal basis with Katy Lindfield, as requested. The outcome of the discussion, which was informed by the applicant's legal advice was that the applicant feels phase two, the basis for this application, requires Regulation 5 support.

In Phase one of the medical examiner programme the medical examiner's role is limited to scrutinising deaths which occur in the Trust hosting the medical examiner office, and CAG has agreed that the legal basis relied on for sharing confidential patient information for those purposes is implied consent. Medical examiner functions relate to patient care in the context of the certification of death and/ or to local clinical audit processes, designed to evaluate clinical performance to inform the management of services.

Phase two extends the programme to scrutiny of deaths in a number of different settings which occur outside the Trust which hosts the medical examiner. It was not considered appropriate to rely on implied consent in circumstances where a patient was not receiving care or treatment from the host Trust immediately prior to their death. As such the applicants, in discussion with DHSC, consider that Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 is the most appropriate legal basis for phase two of the programme.

CAG members considered this response and were content that phase two of the medical examiner programme requires regulation 5 support.

The provisional outcome letter also detailed a number of conditions. These conditions did not require a response prior to support being given but, nevertheless, the applicants have responded to these points. As such a summary of the applicant responses to conditions of support are provided below.

2. **A strategy on how information about the National Medical Examiner system will be disseminated is to be created and provided to the CAG.**

The applicants confirmed that DHSC will be leading on a public campaign on the national medical examiner system. This will not be undertaken until primary legislation is amended, late 2021 at the earliest. NHS England and NHS Improvement are leading on communications to healthcare organisations and staff, and an overview was provided. Template generic information is being provided to all organisations and will be used in a way and manner that is appropriate to that organisation in order to manage local public expectations.

The CAG were happy with the response and no issues were raised.

3. **Patient and public involvement should be undertaken around the processing of confidential patient information for patients who had died out of hospital, if it has not already been done, and that feedback was provided to the CAG**

As part of the operational engagement NHS England and NHS Improvement have worked with representatives from a range of stakeholders from professional and faith groups, as well as looking to include representatives from patient groups. In addition, the applicants have included two lay representatives in their implementation group who provide the lay perspective and challenge from a lay perspective.

Members were content with this response.

4. **Consent should be sought from the next of kin for the continued retention of their details, including their contact details, after their participation in the review has concluded.**

The applicants considered whether it would be possible to offer next of kin the option of deleting their details but considered that is not desirable or feasible. Experience arising from independent inquiries into healthcare suggests it is likely, in future, there will be a requirement in some cases to retrospectively review the outcome of scrutiny by medical examiners. Deleting details of the next of kin could significantly constrain such retrospective review. As the applicants noted in their submission, the participation of next of kin is entirely voluntary, and their contact details will already have been recorded in patient records.

The CAG were happy with this response and no further issues were raised.

5. **Consider whether the patient records can be pseudonymised, such as by removing all identifiers apart from patient NHS number from the record. If this could not be done, then an explanation needs to be given as to why needs to be provided.**

The applicants considered pseudonymisation but felt that pseudonymisation was not feasible. Experience arising from independent inquiries into healthcare suggests it is likely, in future, there will be a requirement in some cases to retrospectively review the outcome of scrutiny by medical examiners. As such, pseudonymisation would introduce an additional layer of bureaucracy and administration for medical examiner offices, which is not provided for within the funding model, and is not practical given the limited staff available. This would hamper such retrospective review significantly.

No issues were raised by the CAG on this response.

6. **The applicant to confirm to CAG if they wish to apply for a waiver from the National Data Opt-Out.**

The applicants registered their interest in applying for such a waiver. In line with previous precedents, to apply for the waiver the applicant should submit an amendment to CAG, together with a paper detailing the justification for such a request. This paper should also include discussion on how applying the national data opt out will impact the work of the national medical examiners system. On submission of the amendment it will be considered by a full committee of the CAG.

7. **Clarification needs to be provided on where data from deaths in the community, e.g. deaths in cottage hospitals, nursing homes, general practice homes, hospices, etc, will be stored.**

The applicants state that medical examiner offices are hosted by acute trusts and will store their data using their trusts' data security and protection arrangements. They will not be storing their records at cottage hospitals, nursing homes, general practice homes, hospices, etc.

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 standard conditions of support as set out below.

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

   Due to the number of organisations involved it is the responsibility of NHS England and NHS Improvement, as controller, to ensure that Trusts hosting the medical examiners meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a Trust.

b. 21/CAG/0040 - Welsh Study of Mothers and Babies. Examining the association between cardiac echogenic foci at the 18-20 week antenatal fetal anomaly scan and cardiac disease in early childhood: An electronic record-linked cohort study. Sub-study 1: Obtaining scan images for further classification of the cardiac echogenic foci

Name	Capacity
Dr Liliane Field	CAG member
Mr. Myer Glickman	CAG member

Ms Clare Sanderson	CAG alternative vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Cardiff University set out the purpose of medical research that aims to examine whether babies with cardiac echogenic foci (CEF) have more adverse outcomes during childhood compared to babies without the marker and whether specific marker characteristics are predictive of these outcomes. The application describes an un-consented sub-study of a larger consented project; The Welsh study of mothers and babies. When first recruited, women gave their consent for the study team to record the presence of markers on the anomaly scan, and to use their NHS number to link these with data on health outcomes from the routinely-collected population-based child health datasets available in Wales. Information on the presence or absence of CEF at the anomaly scan was therefore collected during the original study. The cohort for this sub-study are 616 mother-fetus pairs who had a fetal anomaly ultrasound scan between 2008 and 2011, where CEF were recorded as present. The applicants are requesting support under Regulation 5 to process confidential patient information about these mother-fetus pairs without consent, as the original consent did not cover the identification of certain characteristics of the CEF (multiple versus single; in the right or bilateral ventricles versus the left ventricle; larger versus smaller foci), and applicants will be transferring identifiable information without consent to study clinicians in Cardiff and Vale Health Board and the research radiographer at Betsi Cadwaladr Health Board to identify and code the appropriate scan images. The study did not collect information on the features of the CEF originally, because this was not known to be important when the data were collected in 2008-2011. The applicant has provided justification for why gaining consent for the sub-study is not practicable, and therefore is requesting support for this disclosure. All other elements of the study are undertaken with consent.

CEF are non-structural markers identified at routine 18–20 week fetal anomaly ultrasound scans. Evidence on the clinical significance of CEF is limited, as it is not clear whether CEF is predictive of adverse health outcomes in childhood. Recent studies have suggested that the number, size or location of foci may be important to predict the presence of congenital heart disease and to distinguish between benign and pathological lesions, although these studies had small sample sizes and focused on high-risk populations (pregnant women who had clinical factors that increased the risk of adverse outcomes). Further large population-based studies, which include data on the characteristics of the foci, are therefore needed to fully evaluate outcomes in early childhood. The Welsh Study of Mothers and Babies provides a unique opportunity to address this research gap, by following a large population-based sample of consented mothers and babies to examine whether babies with CEF detected at the 18-20 week scan have more adverse health outcomes during childhood compared to children without this marker. The results of this application will facilitate the

development of clinical guidelines and care pathways during pregnancy and after birth, and provide more accurate information to counsel women and their families.

The applicants, at Cardiff University, already hold identifiable information about 616 mother-fetus pairs who had a fetal anomaly ultrasound scan between 2008 and 2011, where CEF were recorded as present. However, the study does not have the actual images of the ultrasound scan on record. In order to identify additional features of the foci, the applicants will need to obtain the images from the anomaly scans where cardiac echogenic foci were identified. NHS number, name, date of birth, scan date, and woman's study identification number of the eligible cohort will be extracted from the Welsh Study of Mothers and Babies database of identifiable information. 586 images can be accessed from the Synapse system at Cardiff and Vale Health Board, however 30 images are required to be transferred to Cardiff and Vale from Betsi Cadwaladr Health Board. Applicants will disclose the mentioned identifiers regarding the 30 women who were scanned at Betsi Cadwaladr Health Board to the research radiographer at Betsi Cadwaladr, via the secure NHS file sharing portal. The 30 images will be retrieved by the research radiographer, and sent to Cardiff and Vale. Identifiable information will then be deleted by the research radiographer at Betsi Cadwaladr. Applicants will also disclose the mentioned identifiers regarding the remaining 586 women who were scanned at other health boards, and also the 30 scanned at Betsi Cadwaladr, to two named clinicians based at University Hospital Wales, which is part of Cardiff and Vale Health Board, via the secure NHS file sharing portal. The clinicians will code around half of the scans each. They will both code the first 10% of scans and their results will be compared to ensure consistency. Each clinician will therefore have access to the information of 370 women.

The disclosed identifiable information will be used to identify the correct ultrasound scans. The clinicians will then review all 616 images to identify and record the pre-defined foci characteristics. The clinicians will then remove NHS number, name, date of birth, and date of scan from the dataset, and return the data containing foci characteristics alongside woman's study identification number to the applicant at Cardiff University via the NHS secure file sharing portal. The pseudonymised information will then be uploaded by the applicant into the Secure Anonymised Information Linkage (SAIL) databank, linked to the Welsh Study of Mothers and Babies information already held within the databank using the encrypted study identification number, and analysis will be undertaken to examine whether certain foci characteristics are more likely to be associated with adverse outcomes. This application will no longer require support under Regulation 5 at the point the identifiers are removed from the dataset and deleted by the clinicians at Cardiff and Vale health bard, and the applicants estimate that this process could take up to three months.

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

Confidential patient information requested

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

Cohort	616 mother-fetus pairs who had a fetal anomaly ultrasound scan between 2008 and 2011, where a specific cardiac finding ("cardiac echogenic foci") was seen in the baby's heart at the 20 weeks scan All women were recruited into a previous study (the Welsh Study of Mothers and Babies) with consent
Data sources	1. Cardiff university database of Welsh Study of Mothers and Babies. 2. Cardiff and Vale Health Board (Synapse imaging system - fetal anomaly ultrasound scans) 3. Betsi Cadwaladr Health Board (local imaging system - fetal anomaly ultrasound scans)
Identifiers required for identification of correct scan purposes	1. NHS number 2. Name 3. Date of birth 4. Date of fetal anomaly scan 5. Woman's study identification number
Identifiers required for analysis purposes	1. None

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.

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Consider whether the only patient notification should be the website information, instead of the letter.**

The applicant provided a response on 13th April 2021, confirming they are happy to use only the website and Twitter for patient notification instead of a letter, and understood the rationale behind the advice provided by the CAG. The CAG were content with this response.

2. The privacy notice is to be revised.
The applicant has revised their privacy notice displayed on the website. This satisfies the condition applied by CAG, and the Sub-Committee are now content to 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

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. Confirmed (Favourable opinion with conditions) 21 April 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:

Betsi Cadwaladr University Health Board completed their most recent Caldicott Principles in Practice (CPiP) assessment on the 31st of July 2020. They achieved a score of 95.6%.

Cardiff and Vale University Health Board completed their most recent Caldicott Principles in Practice (CPiP) assessment on the 17th of March 2021. They achieved a score of 83.8%. An improvement plan has also been provided, as the threshold score for CAG purposes is 93%.

c. 21/CAG/0054 - A cluster randomised controlled trial to assess the effectiveness and cost-effectiveness of the 'Your Care Needs You' intervention to improve safety and experience of care transitions.Short title: Using routine data to assess the impact of the YCNY Intervention

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Mr Tony Kane	CAG member
Mr Andrew Melville	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Bradford Institute for Health Research (based at Bradford Teaching Hospitals NHS Foundation Trust) set out the purpose of medical research which aims to examine the impact of the 'Your Care Needs You' (YCNY) intervention on unplanned hospital readmissions for patients aged 75 years and over who are discharged to their own homes.

Transitions of care from hospital to home can be risky, especially for older people with multiple health conditions, with up to 1 in 5 people experiencing an adverse event within the first three weeks after leaving hospital. Previous research has suggested that the post-discharge period may be improved by better involving patients and families in their care. This study forms part of a programme of research which aims to develop an intervention to improve the safety and experience of transitions from hospital to home for people aged 75 years and over.

A feasibility study 19/CAG/0105 has already been conducted, which identified that hospital coding did not accurately distinguish people who are admitted from and discharged to their own homes compared to those who are admitted from and discharged to a nursing /care home or other. Applicants only require data on those discharged to their own home, and therefore will resolve this issue by involving a trust employed research nurse to manually check the discharge destination, as this was confirmed to be feasible as part of the previous study. This application is for an RCT of the intervention at 11 acute hospital NHS Trusts, and support is requested for routine clinical data regarding hospital readmissions at 30, 60 and

90 days after discharge of 4,400 patients who have not consented to be extracted and anonymised by Trust staff who are not part of the direct care team, and does not include 1,000 consented patients. Approximately 40 participating wards will be recruited from across 11 acute NHS Trusts in England. Using ward level randomisation, wards will be randomly allocated to one of two trial arms: delivery of the YCNY, or care as usual.

Information Services within each Trust will create a list of patients from participating wards aged over 75 years and who were discharged to 'usual place of residence' as per standard hospital coding. The file will contain NHS number, date of birth, gender, and admission and discharge details, dates of subsequent planned and unplanned admissions and discharges up to 90 days post discharge, and details of whether or not a patient has died. They will calculate age at first index admission. The file will be internally transferred to the Trust employed Research Nurse who will manually check the actual discharge destination after the index stay from the medical records, and record ‘yes’ or ‘no’ for discharged back to own home rather than the actual location. As the research nurses may be defined as outside the direct care team, an application to CAG has been made. The applicants have commented that clinical staff are unable to undertake the data extraction as manual checking of actual discharge location is quite labour intensive, and direct care team staff already face considerable workload pressures. The PACT research team will notify the individual trust research nurses of patient opt outs and ask for those patients to be removed. The research nurse will then delete dates of birth and NHS numbers and remove all data for patients who were not discharged to their own homes. The file can be considered anonymous, as the recipients will not be able to re-identify any patient. The file will be transferred to the PACT research team at Bradford Teaching Hospitals NHS Foundation Trust. This will then be onwardly disclosed to the York Trials Unit at the University of York for analysis.

A recommendation for class 1 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	4,440 patients who were discharged to own/carer’s home and aged 75 years or older at the index admission
Data sources	Patients records (electronic or paper as appropriate) from approximately 40 participating wards across 11 acute NHS Trusts; • Bradford Teaching Hospitals NHS Foundation Trust • Calderdale & Huddersfield NHS Trust

	• Doncaster & Bassetlaw Hospital • Harrogate and District NHS Trust • Hull University Teaching Hospital • Sheffield Teaching Hospital • York Teaching Hospital • Royal Blackburn Teaching Hospital • Lancashire Teaching Hospital • South Tyneside and Sunderland NHS Trust • Newcastle upon Tyne Hospital Trust
Identifiers required to extract an anonymised dataset	1. NHS Number 2. Hospital ID Number 3. Date of birth 4. Date of death 5. Gender 6. Postcode (unit level) 7. Address of patients' usual residence 8. Date of admission to hospital 9. Ward admitted to 10. Date of discharge 11. Dates of re-admission

Identifiers required for analysis purposes	1. Gender 2. Age 3. Date of admission to hospital 4. Ward admitted to 5. Date of discharge 6. Dates of re-admission This can be considered anonymous for analysis purposes, as the researchers will not have any way to re-identify the patients.

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 update the patient information leaflet with the standard wording regarding CAG as described above, and provide an updated version.**

The applicants amended the wording as suggested and version 2 of the leaflet was provided. The Sub-Committee were content with this response.

2. **Please consider implementing the national data opt out, or provide a justification as to why this cannot be implemented.**

The applicants have spoken to several NHS Trust sites who also consider that the national data opt out could be easily applied. Therefore the applicants agree with CAG and will ensure that it is applied to the study. The data flow diagram is updated to reflect this change and this has been provided. The Members were content with this response.

3. **Please provide a Favourable opinion from the REC regarding this CAG application, which we understand to be an amendment to the RCT, when available.**

The applicants provided a favourable opinion (regarding the substantial amendment) from the REC to the CAG inbox on 28 May 2021.

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: Favourable opinion regarding related amendment 21 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. Security assurances are required for the 11 sites where the data extraction take place. Support will be based on confirmation that the DSPT at the site will be complied with. However, as this is more than 5 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.

d. 21/CAG/0060 - A pan cancer programme of tumour typing (version 1)

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
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Context

Purpose of application

This application from Leeds Teaching Hospitals NHS Trust set out the purpose of medical research that seeks to provide specimens to their commercial partner, TriStar, who will house the samples to be used in a range of analyses as part of drug development programmes undertaken by pharmaceutical companies.

The applicants have previously undertaken a pilot study, which sought to gain further understanding around the genetic blueprint defects and pathways leading to abnormal protein expressions in patients with ovarian cancer, supported by the CAG under reference 19/CAG/0008. The applicants are now seeking to expand this model to include 200 other cancer types, including breast, lung, skin, reproductive, blood and gastrointestinal cancers. The outlook for patients diagnosed with the 200 cancer types is poor. Lung cancer alone is responsible for 35,300 deaths each year, with only 9.5% of patients surviving 10 years or more after diagnosis. Low cancer survival rates occur for a number of reasons, such as late diagnosis, meaning that a diagnosis is made after the cancer has spread and the cancer is at a more advanced stage, where therapeutic intervention is less effective. A better understanding of the genetic blueprint defects and the pathways leading to abnormal protein expression may help to develop more effective targeted therapies.

In this project, the applicants will provide surplus archival cancer tissue samples and electronically scanned tissue slides, alongside anonymised case-specific demographic annotations to a commercial partner, TriStar, who are also funding the project. In turn, TriStar will then distribute these materials and images to pharmaceutical companies, who will use these materials in cancer drug development programmes. Staff within Leeds Teaching Hospitals NHS Trust, but who are not considered to be members of the direct care team, will identify suitable patients from electronic patient records within the same Trust. Tissue blocks will be retrieved and, if the samples are deemed suitable following review by the Chief Investigator, the blocks will be transferred to TriStar alongside anonymised information. This means that only anonymised information will be disclosed outside the Trust.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over, treated for cancer at Leeds Teaching Hospitals NHS Foundation Trust. 12,000 cases, offering a cross-representation of different cancer types and sub-types, will be selected. The study is expected to last for five years and cases between 1991 and 2021 may be selected, however the applicant

	expected that cases between 2005 and 2025 were most likely to be selected.
Data sources	1. Electronic patient records at Leeds Teaching Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Date of death
Identifiers required for analysis purposes	1. Ethnicity 2. Gender 3. Age in years
Additional information	Anonymised information only will be disclosed outside Leeds Teaching Hospitals NHS Foundation Trust

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.

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. Clarify whether patients' sex or gender would be shared with TriStar.

The applicant clarified that gender would be shred, and age in years. The Sub-Committee were content with this response.

2. The patient notification materials need to be revised as follows;

- **a. The role of TriStar as a commercial partner needs to be emphasised.**
- **b. It needs to be explained how the collaboration with TriStar will benefit both the University of Leeds and the public.**
- **c. The steps taken to ensure the confidentiality of patient data needs to be explained.**
- **d. Provide further details on where the website notification will be displayed.**

The applicant has provided updated notification materials with appropriate changes as requested, and stated that the notification will be displayed on the LTHT website (https://www.leedsth.nhs.uk/research/). The Members were content with this response.

2. Clarify whether the National Data Opt-Out would be applied.

The applicants have explained that The National Data Opt-Out will not be applied in this instance as patients will have until the 3rd of September 2021 to remove the use of their data/tissue whereas compliance with the National Data Opt-Out does not come into effect until 30th September 2021. The Members were content with this response.

3. **Provide further details on the patient and public involvement undertaken, including how the engagement with patients has been expanded to match the expanded cohort.**

The applicant explained that the project was presented to a local Patient and Public Involvement Group during a dedicated virtual meeting involving a PowerPoint presentation. The Group acknowledged the success of the ovarian cancer pilot study and were very supportive of the proposed follow-on study expanding to cover a range of malignancies. No issues or concerns were raised. The Cag Sub-Committee were content with these responses.

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: 19 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 review for Leeds Teaching Hospitals NHS Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 06 May 2021).

e. 21/CAG/0001 - Optimum Patient Care Research Database (OPCRD)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Mr David Evans	CAG member
Dr Liliane Field	CAG member
Mr. Myer Glickman	CAG member
Mr Tony Kane	CAG member
Professor Jennifer Kurinczuk	CAG member

Mr Andrew Melville	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Caroline Watchurst	Confidentiality Advisor

Context

Purpose of application

This application from Optimum Patient Care (OPC) Ltd set out the purpose of creating a real-world, longitudinal research database that provides anonymised data to support scientific, medical, public health and exploratory research.

The OPC database holds de-identified data provided from participating GP practices. Data collection for OPCRD is conducted by Optimum Patient Care Limited (OPC), a not-for-profit social enterprise that provides quality improvement programmes for chronic conditions and research support services to GP practices across the UK. OPC quality improvement programmes and research support services are provided at no cost to participating GP practices under a service agreement.

As part of the service agreement, GP practices agree to contribute de-identified patient data to OPCRD for quality improvement and for research purposes. This includes de-identified longitudinal primary care patient data (derived from both electronic health records (EHR) data and from patient questionnaires delivered as part of quality improvement) and data linked from other health-related datasets e.g. secondary care data. The population base for OPCRD is all patients at contributing GP practices, excluding patients who have opted-out or refused consent for data sharing for care planning (quality improvement) or for research purposes. Data recorded or coded as “Confidential” in patient EHR and sensitive special category data which are not relevant for quality improvement or research, such as sexually transmitted diseases (STDs), termination of pregnancy, fertility treatment, marital status, convictions/imprisonments, physical/psychological/sexual abuse, etc. are not collected by OPC or for OPCRD.

Data contributed to OPCRD enables research into all chronic conditions in primary care. OPCRD has received data contributions from over 750 GP practices and currently holds de-identified data for approximately 9.6 million patients or data subjects. Over the last calendar year of 2019, the OPCRD has received data contributions from over 320 GP practices, accounting for over 3.6 million non-identifiable patient records. Anonymised data only is supplied to researchers for use in ethically approved scientific and public health research. All research conducted using the OPC database must also be approved by the Anonymised Data Ethics and Protocols Transparency committee (ADEPT). Proceeds from OPCRD data access fees and detailed feasibility assessments are re-invested into OPC services for the continued

free provision of patient quality improvement programmes and research support services for contributing GP practices.

OPCRD receives pseudonymised de-identified electronic health records data and questionnaire data of patients from participating GP practices. This may include de-identified questionnaire data for any condition or disease. OPCRD may also receive anonymised linked data from other health-related datasets and registries for patients from consented contributing GP practices. This may include Hospital Episode Statistics (HES), Scottish Morbidity Record (SMR), Patient Episode Database for Wales (PEDW), Northern Ireland Hospital Statistics (NIHS).

The applicants are seeking support under s251 for the disclosure of confidential patient information from participating GP practices to the Harvey Walsh Secure Portal. Harvey Walsh will then collect all patient identifiers and Study IDs received from the participating GP practices and combine them into one file. Harvey Walsh will then transfer the patient identifiers and Study ID to NHS Digital via the Health and Social Care Network (HSCN). NHS Digital will match the dataset to HES and return de-identified HES data, with Study IDs, to Harvey Walsh via the secure HSCN. Harvey Walsh will use the Study IDs to link the de-identified GP electronic health records data, received from OPCRD, with the de-identified HES data to create the linked OPCRD-HES dataset, which is stored securely on OPCRD-NEXUS. No patient identifiable data will be held in OPCRD or OPCRD-NEXUS. The applicants will request linkages from NHS Digital on a quarterly or six-monthly basis.

The applicants acknowledged that linkages to SMR and NIHS are outside the remit of Regulation 5 ('s251' support). Support for linkage to PEDW data was not sought within this application.

A recommendation for class 1, 2, 3, 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 registered at contributing GP practices, unless patients have objected to sharing of their data for use in research or care planning.
Data sources	1. Electronic patient information provided by participating GP practices 2. HES datasets (HES Admitted Patient Care, HES Outpatient Care, HES Critical Care, HES Accident and Emergency (A&E), HES Emergency Care Data Set

	(ECDS) and HES Civil Registry (Deaths)) held at NHS Digital
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	No identifiers will be retained for 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. **Provide reassurance that the two databases held by the Harvey Walsh Secure Portal, one containing identifiable data and the other containing de-identified data, would be held completely separately and could not come into contact with each other to allow accidental or deliberate re-identification; and a description of the measures providing this assurance.**

The applicants advised that the Harvey Walsh Secure Portal, which will receive confidential patient information under Regulation 5 support and will transfer the identifiers to NHS Digital for data linkage, is held completely separately from the OPCRD-NEXUS database.

The OPCRD-NEXUS database will hold the de-identified linked data for research. The Harvey Walsh Secure Portal is held on a separate dedicated server that resides on the Health and Social Care Network (HSCN) provided by PIKSEL, who are recognised as a trusted technology partner by the NHS. Access to this server is only available to pre-approved Harvey Walsh staff via a dedicated VPN connection to the server. OPCRD-NEXUS is held on a separate secure dedicated data server on the HSCN hosted by UK-FAST for paramount data security.

The Harvey Walsh Secure Portal and OPCRD-NEXUS are thus two separate entities and are held on separate servers at two separate distinct locations. There is no transmission of information between the two databases.

The CAG noted this information and was satisfied by the response.

2. **Provide further clarification on the identifiers that will be retained, specifically whether patients' year of birth, date of death, GP registration, occupation, gender, ethnicity, district postcode or unit level postcode will be retained.**

The applicants explained that OPCRD has a REC favourable opinion to hold patients' year of birth, date of death, GP registration, district level post code, gender, occupation, and ethnicity. This information will be retained from the OPCRD data. These identifiers will not be retained

from the HES data supplied for linkage. The CAG noted this information and raised no further queries.

3. **Provide further details on the process of redacting free text, including the success/failure rate of the method used, and how the applicants have ensured the efficiency of the two-stage process.**

4. **Provide further details on the associations that will be redacted from free text following consultation of the 'global dictionary of known associations', e.g. will the names of organisations such as NHS Trusts and GP practices be removed.**

The applicant provided a combined response to queries 3 and 4.

The applicant explained that, as part of the data collection and de-identification process at each OPCRD contributing practice, free text data undergoes a 2-stage robust redaction process. This includes an initial redaction, where items of confidential patient information are removed from any free text extracted. Identifiable texts are removed and replaced with the term "redacted."

The second stage is an enhanced redaction. The redacted data is referenced against a global dictionary of known names, associations and places, which includes the names of GP practices, hospitals and NHS trusts. Any potentially identifiable information is removed. Data quality checks are also conducted to monitor for any patient identifiable information when the de-identified data (which includes redacted free text) is received at OPC before the data is imported into OPCRD.

The redaction process used by OPC is based on redaction technology developed and used by OPC in Australia, where OPC provides an accredited quality improvement and clinical audit programmes for GP and specialist practices. In Australia, primary care electronic health records (EHR) largely contain uncoded and unstructured free text data, with limited clinical coded data. The OPC redaction process has been extensively tested and used in GP practices in Australia to securely redact and collect free text from GP EHR. To date, there have been no reported failures. For use in the UK, the redaction process was made more stringent thus in effect over-redacting, to ensure the process was robust and reliable. There have been no recorded failures of the redaction process in the UK. OPC continues to monitor each de-identified data extract received from contributing practices.

The CAG noted that, should any items of confidential patient information remain in the free text after it has been through their process, then there will be no legal basis for this under the common law duty of confidentiality and such a breach should be reported immediately to CAG for consideration of proposed remedial action.

5. **Confirm that data transferred outside the UK will be sufficiently anonymised and provide details on how this will be assured.**

The applicant confirmed that anonymised data only will be transferred outside the UK. Data will be sufficiently anonymised according to the Information Commissioner's Office (ICO) anonymisation code of practice. No record level data will be transferred outside the UK. All data transferred will be fully anonymised i.e. aggregated and derived data.

6. **Confirm that at least two lay members will be included on the steering committee and ADEPT committee.**

The applicant confirmed that at least two lay members will be included on the steering committee and ADEPT committee to provide the pre-requisite patient and public perspective. The CAG noted this information and raised no further queries.

7. **Undertake patient and public involvement around the specific issue of the use of confidential patient information without consent. An outline plan needs to be provided in the response to the provisional outcome and feedback from the patient and public involvement provided at the first annual review.**

The applicants explained that they will conduct a patient and public involvement and engagement (PPIE) event, using an independent panel, to explore the patient perspective on the use of confidential patient information without consent. This is planned to take place in April or May 2021 and will include 10 patients and lay people. The panel will focus on the use of identifiers for OPCRD-NEXUS data linkage.

Representatives from OPC and Harvey Walsh will be present at a later stage of the meeting for the panel to ask questions about the project, and to clarify or explain any aspects of the process. The panel will then provide their feedback, which will be used for improvement, and will be reported in the annual project report submitted to CAG. The PPEI panel will also meet at least annually or sooner if there is a significant change in the process, especially if there is any change in data flow. The above process will be repeated for each PPEI meeting, and the panel feedback will be used for improvement. The CAG noted this information and raised no further queries.

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 is given for the processing of redacted free text. Any failures of the redaction process which result in identifiable data being shared should be reported to CAG immediately for consideration of proposed remedial action.

2. The potential change to the data flow, so that GPs can send confidential patient information to NHS Digital directly, needs to be explored by the applicants and reported to the CAG at the first annual review. If the data flow cannot be revised, a justification for why this could not be given will need to be provided.

3. Favourable opinion from a Research Ethics Committee. Confirmed 06 July 2020

4. 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: NHS Digital and Harvey Walsh Ltd (by check of the NHS Digital DSPT spreadsheet on 25 January 2021) have confirmed 'Standards Met' grade on DSPT 2019/20.

Participant GP practices – Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

2. New Amendments

a. 19/CAG/0223 – TwinsUK: Phenotypic enrichment of the TwinsUK cohort through linkage to electronic health records and other databases.

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from King's College London to NHS Digital, NHS Wales Informatics Service, GP Practice software providers and the Department for Education to facilitate linkage with primary and secondary care records, cancer registration, mortality data and information on educational attainment.

TwinsUK will be taking part in a research initiative called the UK Longitudinal Linkage Collaboration (UK LLC), which has its own CAG approval in place, reference 21/CAG/0044. The UK LLC is a new research infrastructure designed to inform the UK's research response to the Covid-19 pandemic through supporting the Longitudinal Health & Wellbeing National Core Study. The TwinsUK participant information materials have been updated to include information about the UK LLC. This amendment therefore sought support for these updated patient notification and opt out materials.

The opt out options provided enabled TwinsUK participants to opt out of different linkages undertaken as part of TwinsUK, which would then also opt them out of the LLC. However there is not an option for participants to only opt out of LLC. The applicant explained that this has been thought through, and it was considered it would be a lot more complicated for the study to enable an LLC specific opt out option, and they do not expect to receive any additional opt out requests due to the additional LLC processing, above what would be expected regarding only the TwinsUK study. Therefore this is not expected to cause TwinsUK to have lots of people opting out of the study in order to avoid being part of LLC.

These notification materials are those referred to in previous CAG amendment, outcome provided 27 April 2021.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair's Action. The Chair agreed that the notification materials and opt out options provided were appropriate, and understood the

justification provided by the applicant surrounding not specifically providing an LLC only opt out option.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.
2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 21 April 2021

b. 21/CAG/0008 – Clinical Practice Research Datalink (CPRD)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Mr David Evans	CAG member
Dr Liliane Field	CAG member
Mr. Myer Glickman	CAG member
Mr Tony Kane	CAG member
Mr Andrew Melville	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Amendment request

An amendment was submitted to add the following datasets to the CPRD master dataset list for linkage by NHS Digital:

1. SGSS – Second Generation Surveillance System – from PHE
2. CHESS – COVID-19 Hospitalisation in England Surveillance System – from PHE
3. NPEx – National Pathology Exchange COVID-19 Pillar 2 test data – from NHS Digital
4. HES-MSDS – Maternity Services Data Set – from NHS DigitalNHSBSA – Medicines dispensed in primary care – from NHS Digital
5. NCARDRS – National Congenital Anomaly and Rare Disease Registration Service – from PHE (CAG 10-02(d)/2015)
6. NAAASP – NHS Abdominal Aortic Aneurysm Screening Programme data – from PHE

Confidentiality Advisory Group advice

Support for the amendment was initially withheld until conditions of the initial support were complied with. These conditions have now been met and therefore the sub-committee raised no further issues with the amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from REC Received
2. Continual achievement of ‘Standards Met’ in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support.

Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met’ for the duration of support, and at time of each annual review. The 19/20 DPST submission NHS Digital has been confirmed as ‘standards met’.

c. 19/CAG/0211 – Improving the effectiveness of cancer multidisciplinary team meetings (MDTMs) in Surrey and Sussex

Name	Capacity
Ms Katy Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow members of the research team to access confidential patient information at participating sites in order to extract a pseudonymised dataset, Support is also in place for any incidental disclosures of confidential patient information that may be made during the observations of MDTM meetings.

In this amendment, the applicants are seeking to remove the oeosphago-gastric cancer and hepatobiliary and pancreatic cancer tumour pathways, reducing the number of tumour pathways included from three to one. The project will now focus on lung cancer only and will comprise of 8 MDTs across the 7 NHS Trusts involved in the project, rather than the 11 MDTs supported originally.

The applicants also seek to change from a pre-post design to a descriptive observation design, where data will be collected for 10-12 weeks continuously. This will be comprised of 4 weeks before and 6-8 weeks during and after implementation of the new protocol. The sample size will also be reduced. The original sample was based on 25 patients per meeting per week for lung cancer. The applicants now expect that 15-25 patients per meeting per week will be included, to allow for the variability seen this year in cancer referrals. The estimated sample size has reduced from 2440-3660 to 1200-2400.

The study end date will also be changed from 31 August 2021 to 31 October 2021. This extension is required due to delays caused by the Covid-19 pandemic.

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. Favourable opinion from a Research Ethics Committee. Confirmed 07 April 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. Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

d. 20/CAG/0133 – Yorkshire Specialist Register of Cancer in Children and Young People

Name	Capacity
Mr Patrick Coyle	CAG Vice Chair

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information between University of Leeds and Local NHS Trusts, EMIS, TPP, NHS Digital, Public Health England, Department of Education and Department of Work and Pensions, to examine delays in diagnosis and long-term morbidity using routine NHS datasets.

In this amendment, the applicants are seeking support to extend their current research, which examines the outcomes of patients diagnosed with cancer during their childhood and adolescent years, by making two changes.

In order to facilitate a programme of research assessing the prevalence of metabolic late effects amongst a cohort of long-term childhood and young adult cancer survivors (CYACs) in the YSRCCYP, the applicants intend to obtain a bespoke download of data from the Leeds Teaching Hospitals Trust PPM platform. This will require the collection of specific risk markers for cardiovascular disease plus metabolic factors associated with metabolic syndrome and type II diabetes, including HBAC1 levels, lipid profile (total cholesterol, serum triglycerides, high-density lipoprotein (HDL) and low-density lipoprotein (LDL), blood pressure, anthropometric measurements such as weight, height and waist circumference. The applicants note that the collection of some variables, such as weight and waist circumference measurements, may need to be manually extracted from electronic patient records and forms. A range of additional biomarkers of cardiovascular risk, including inflammatory markers, such as C-reactive protein (CRP) and past medical history of electrocardiograms (ECG), will also be collected.

The applicants also seek support to conduct a data linkage to ChemoCare, an electronic chemotherapy prescribing system, in order to examine the impact of dose intensity on the survival of teenagers and young adults with cancer. This will enable the researchers to compare the utility of ChemoCare data to the data already obtained from the national Systemic Anti-Cancer Treatment (SACT) dataset. It will also provide the researchers with more detailed treatment data than that obtained from the SACT.

The applicants also seek to record additional information on whether patients tested positive for Covid-19. If so, the date this diagnosis was confirmed and whether patients were advised to shield will be collected. This is to enable analysis of the impact of Covid-19 on cancer treatment for children and young people.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's action. The Vice Chair raised no concerns about the amendment and was supportive of it.

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. See section below titled 'security assurance requirements' for further information. The NHS Digital DSPT submission for University of Leeds (2019/20), NHS Digital (19/20), EMIS (19/20), Public Health England (2019/20) and TPP (19/20) were confirmed as 'Standards Met' by NHS Digital (by check of DSPT tracker on 09 April 2021).

3. Annual Review Approvals

18/CAG/0066	United Kingdom Childhood Cancer Study
18/CAG/0063	National Early Inflammatory Arthritis Audit (NEIAA)
16/CAG/0091	Investigation into predictors of diagnosis in PAH patients
18/CAG/0126	Connected Health Cities: Data linkage of urgent care data
19/CAG/0161	CRYOSTAT-2

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