Health Research Authority

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

May 2023

1. New Applications

a. 23/CAG/0005 - A randomised controlled trial of no routine gastric residual monitoring to guide enteral feeding in paediatric intensive care units

Name	Capacity
Professor Will Bernal	CAG Alternate Vice Chair
Dr Katie Harron	CAG Member
Professor Sara Randall	CAG Member
Mr Marc Taylor	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from Edge Hill University set out the purpose of medical research that seeks to determine whether or not measuring the stomach contents of critically ill

children receiving invasive breathing support impacts on the length of time the child spends on breathing support and their calorie intake.

Paediatric Intensive or Critical Care (PICU) provides care for children who require specialist care for serious medical or surgical conditions and may require mechanical ventilation. Providing adequate nutrition is a key component of care. The sickest children may require para-enteral feeding and other feeding via a nasogastric tube. For tube-fed patients, it is standard practice to aspirate the stomach contents (called gastric residual volume or GRV) before the next feed to check the volume that remains and to make a visual assessment of its composition and status, as these may indicate if something is wrong. The residual may then be returned to the stomach or discarded depending on local guidelines and clinical opinion. The volume of enteral food to then give may then be determined by how much was left from the earlier feed. The practice of GRV measurement in critically ill children is not evidence-based and there is growing concern that GRV may provide little benefit to patients.

The applicants aim to conduct an evaluation to assess the clinical benefits of intervening or not, and the cost-effectiveness of such practices. Eligible patients will be randomised to one of two groups. The intervention arm will not have GRV measurements taken and will be monitored for signs of feed intolerance using clinical signs only. The control group will have GRV measures taken. Due to the emergency nature of admission to PICU, patients will be randomised to either the intervention or control group before consent is sought. Participating NHS trusts will send confidential patient information to ICNARC. ICNARC will disclose confidential patient information to PICANet for linkage to baseline characteristics, treatment and outcome data. ICNARC will also disclose confidential patient information to NHS Digital for linkage to the Civil Registrations Dataset and HES, and to Digital Health and Care Wales for linkage to Patient Episodes Data. ICNARC will combine the data with data from the GASTRIC-PICU trial database and pseudonymise the dataset. Pseudonymised data only will be shared with the London School of Hygiene and Tropical Medicine for analysis.

For most patients, the applicants will seek consent from patient or their parents before they are discharged. However, some patients will be discharged or die before consent can be sought. For these patients, research staff, who are part of the direct care team, will telephone and send letters to parents of patients discharged home prior to consent to inform them about their child being enrolled in the study. If patients or parents do not respond within 4 weeks to register an opt-out, their data will be included.

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 between 37 weeks and 16 years, who are receiving invasive mechanical ventilation (with extubation not planned in the next 48 hours), and where the intention is to start feeding via the gastric route (including gastrostomy). 4700 patients will be included in total. The applicants expect that most patients will be recruited in England and that 4500 patients from England and Wales will be included. Around 10-12% of these patients will be included under s251 support.
Data sources	1. PICANet dataset, held at University of Leeds 2. Civil Registrations Dataset and HES, held by NHS Digital 3. Patient Episodes Data for Wales, held by Digital Health and Care Wales
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Date of death 2. 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. **The poster and the letter to bereaved family members needs to be revised as follows:**

    a. **Details on the patients included in the research need to be provided**
    b. **Details on the data that would be collected, that this includes confidential patient information, and how the data will be used, need to be provided**
    c. **Information on how patients can opt-out or parents could object to use of their child's data need to be provided.**
    d. **Contact details for registering dissent/opt-out need to be provided. The CAG usually expects that email, telephone and postal details are given.**
    e. **The poster and letter need to be reviewed during patient and public involvement activities and revised as appropriate.**

The applicants provided revised documents. The documents and consent procedures had been revised by the Parent Advisory Group, and feedback from the Group was provided.

2. **Provide clarification on whether the specific issue of the use of confidential patient information without consent had been discussed during patient and public involvement. If no patient and public involvement has been undertaken around this issue, the project should be discussed with relevant patient groups and feedback provided to the CAG.**

The applicants confirmed that this specific issue had been discussed with the Parent Advisory Group. The Group were asked whether it was acceptable to collect patient NHS numbers, dates of birth, sex and postcodes for patients, without seeking consent. Additional feedback was provided.

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 09 May 2023.**

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 21/22 DSPT reviews DSPT for PICANet (University of Leeds, NHS Digital and ICNARC were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 January 2023).

   Digital Health and Care Wales - CPiP in place.

b. 22/CAG/0150 UK STORE - United Kingdom Register of Stored Ovarian and Testicular Tissue (Research)

Name	Capacity
Ms Clare Sanderson	CAG Alternate Vice Chair
Dr Harvey Marcovitch	CAG Member
Mrs Diana Robbins	CAG Member
Mr Dan Roulstone	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from the University of Leeds set out the purpose of medical research which aims to establish a research database of all stored ovarian and testicular tissue obtained from young people in the UK.

The UK Register of Stored Ovarian and Testicular Tissue (UKSTORE) will be the first registry of stored ovarian and testicular tissue collected from young people in the UK. The registry will be used to support service development, evaluation and research.

The data will be obtained from all centres where ovarian and testicular tissue were collected and stored from patients aged 0-24 years. Storage centres will identify eligible patients via clinical records and local databases, and the confidential patient information transferred to UKSTORE. Confidential patient information will be used to perform data linkage to extract relevant data from existing databases. Additional data will be collected from patient medical records, directly from patients and from their GP's.

UKSTORE data is divided into two main components; data captured without consent and data captured only with written informed consent. Data captured without consent comprises most data for UKSTORE. This is referred to as “core data” and includes confidential patient information. “Core” data will be captured for all patients who preserve tissue in the UK and are aged 0-24 when they do so. “Core” data will be captured for retrospective (who have already had tissue preserved) and prospective patients (who preserve tissue after UKSTORE has been established).

Data captured with informed written consent will only be sought from patients who are aged 16 years and above and is referred to as “additional data.” This data is focused on reproductive outcomes. Patients aged 16 years and over in England will be invited to consent when they attend a follow up appointment, or at any other appointment as deemed appropriate by their clinical team. Patients who are no longer attending routine follow up appointments will be sent an approved UKSTORE information sheet about additional data capture and invited to contact the tissue storage centre or UKSTORE directly, to give informed consent. This information will be sent alongside the next routine correspondence sent from tissue storage centres that confirms ongoing tissue storage. Storage centres will perform an additional safety check to screen and exclude patients they know have registered an opt out.

A recommendation for class 1, 2, 4, 5, 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 whose ovarian or testicular tissue was collected when they were aged 0-24 years. The timeframe for inclusion will go back to the first point at which tissue preservation began so that it includes all patients (whole population). Records in England go back to 2013.
Data sources	1. Patients clinical records, including regional paediatric, teenage and young adult cancer centres 2. NHS centres in the UK that store ovarian and testicular tissue harvested from people when they were aged 0- 24 years. 3. Patients (self-reported) 4. NHS England (previously NHS Digital) held datasets: a. Cancer registry b. Cancer pathway c. SACT d. RTDS e. Hospital Episode Statistics (HES) admitted care f. National Disease Registration Service for patients with cancer, congenital anomalies and rare diseases (NCARDRS) g. National Cancer Registration Analysis Service (NCRAS) 5. GP data via GPES 6. External disease registries, including: a. The Welsh Cancer Intelligence & Surveillance Unit (WCISU)

	b. The European Society for Blood and Marrow Transplantation (EBMT) Registry. United Kingdom Primary Immunodeficiency (UKPID) Registry. c. The British Society for Paediatric and Adolescent Rheumatology (BSPAR). d. The National Haemoglobinopathy Registry (NHR).
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number 4. GP Registration 5. Date of birth 6. Date of death 7. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – unit level 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice

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. **Provide a rationale for collecting the large quantity of participant data sought.**

The applicants advised that the data required had been reduced to the minimum needed to meet national and international standards. Justification for each item required was provided. The CAG noted this information and raised no further queries.

2. **Provide details on how it will be ensured that third parties applying to use the UKSTORE dataset will use the data for medical purposes only.**

The applicant provided the data access policy, which set out how data release would be considered and managed. The CAG reviewed this information and agreed that the criteria applied were appropriate.

Members noted that, in some special cases and with appropriate ethics approval, identifiable data may be released to allow data linkage to be carried out either in a third-party safe haven (Trusted Research Environment) or within an organisation that has suitable security and data protection standards to process UKSTORE data. It is envisaged that such an organisation would be managed by governmental organisations or national health services. Members asked for clarification on whether these applications would also come to the CAG for review.

The applicants advised that it may, occasionally, be necessary for a very limited set of personal data to be processed by an authorised third party, such as NHS England, to enable third parties to study health and social outcomes, but only with the appropriate regulatory permissions. This would require third parties to apply to CAG for s251 support. The CAG noted this information and raised no further queries.

3. **Clarify why consent for core data could not be obtained at the same time as consent was obtained for additional data.**

The applicant advised that consent for additional data would also be sought once patients had reached the age of 18 years. Core data would be captured at the point of tissue harvest, which was most likely to occur between the ages of 0-16. Waiting until all patients turn 16 to invite them to consent would create undue delay and result in an incomplete database unsuitable for robust research.

The CAG noted that this query may have been unclear. The CAG was not asking for patients to be consented at the time the core data was initially collected, but that the core data was originally collected under s251, and consent sought for the core data when patients were contacted for consent for the additional data. This would remove the reliance on support under s251 for the core data. Members requested further details on why it was not feasible to seek consent for the core data when contacting patients at age 18 for the additional data.

The applicants explained that the proposed use of patient information without consent is essential for improving patient care and serving the wider public interest. Currently, there is a serious disadvantage for children who undergo this procedure

because their clinical outcomes are largely unknown. The data collected by UKSTORE will be used to identify who is most likely to benefit from tissue preservation and for whom it represents an unnecessary and potentially risky procedure. It is important to capture whole population data to reliably and robustly answer these urgent questions. Therefore, an opt-out model is the most appropriate and efficient method of ensuring the primary and secondary research aims are met.

If patients aged 16 or above give informed consent for capture of 'Additional' data, they will also receive information on 'Core' data capture, explaining how to opt-out if they wish. This approach will provide patients with a choice while also ensuring that UKSTORE can continue to understand how patients' needs change over time and the impact of tissue preservation on long-term clinical outcomes.

A consent model for ongoing data capture would require correspondences at multiple time points as patients turn 16, which would present an impossible administrative and financial burden to clinical services. Switching to a consent model for those patients who do give consent for 'Additional' data capture, whilst retaining reliance on section 251 for those who do not give consent, means maintaining two separate cohorts of patients which will inevitably create inefficiencies and complexities to manage the dataset effectively within a small resource with the additional risk that some data could be compromised within the register.

Furthermore, obtaining written informed consent for 'Core' data at the same time as consent for 'Additional' data may confuse patients and result in lower consent rates, negatively impacting the quality and completeness of UKSTORE data. For example, patients may not fully understand the difference between the two data sets or may feel overwhelmed by too much information at once. This is particularly relevant to patients who are not in regular follow up and whose priority is to receive direct clinical care when they re-engage with the clinical service. The CAG noted this and raised no further queries.

4. **Justify why the identifiers and clinical data are held within the same database.**

Patient identifiers will be held in a separate table of the database from the clinical data, with the capacity for linkage using a unique identifier created at enrolment. Only key staff, such as the UKSTORE Data Manager, will have access to the table containing identifiers. All derived datasets for analysis will be pseudonymised. The CAG noted this and raised no further queries.

5. **Justify why the research team could not remove the data from the study instead of anonymisation, should patients opt-out of use of their data.**

If a patient, (or their parent / carer), requests that their personal identifiers are no longer processed, their record within the UKSTORE registry will be de-identified.

The CAG agreed that the reason for retaining anonymised data, rather than deleting patient records should they opt-out, had not been provided.

The applicants advised that maintaining anonymised data on the entire population is vital to accurately report the impact of treatment and care on long-term outcomes for survivors. Patients were able to opt-out, but stated that retaining anonymised data was essential for the betterment of all children who store tissue. The CAG noted this and raised no further queries.

6. **The patient notification materials need to be revised as follows:**

    a. **The explanation of the CAG role and section 251 needs to be included, as given above.**

The applicants provided the text to be included in the patient notification materials.

    b. **The opt-out process needs to be clearly described and made obvious in the notification materials.**

The applicants provided the text to be included in the patient notification materials.

    c. **A link to the website information, and telephone and email contacts need to be included.**

The applicant advised that all patient notification materials will contain a link to the UKSTORE website and email and telephone contact details.

The CAG agreed that it was not clear what patients needed to do if they did not want their data to be processed. The patient notification materials needed to be revised to contain a statement that patients can contact the registry directly and ask for their data to be removed. Members asked for confirmation that the website will contain the same statement about opt-out.

The applicants advised that the patient information leaflet were amended to include a statement that they can contact their doctor or the UKSTORE directly using the details

on the leaflet. The same statement would be added to the website. The CAG noted this and raised no further queries.

7. **Please clarify the use of the opt out form, and if this is planned for patient use, please consider removing this form from the process to make it easier for patients to opt out.**

The applicants advised that the primary purpose of the optout form is to record the level of opt-out requested by patients, as patients are given a choice on whether to withdraw all or part of their data. Patients are not asked to complete the form and it will be completed by application staff. The CAG noted this and raised no further queries.

8. **Clarify whether the website was to be updated in due course.**

The applicant confirmed that the website will be updated as the project progresses. The text of the patient information materials and statement on opt-out were provided. The CAG noted this and raised no further queries.

9. **Continue engagement with the Patient and Public Involvement group and provide the CAG with feedback from discussion of the volume of data collected.**

The applicant advised that they are creating a PPIE group to support registry activities. A follow-up call was held with previous PPIE volunteers to update them on the progress so far. A full outline of the data to be collected was provided at previous meetings, including a list of data fields. No concerns were raised. The CAG noted this and raised no further queries.

10. **Increase lay representation in both the steering group as well as data release committee.**

The applicant advised that a lay representative will be included on both the steering group and data release committee. An update will be provided to the CAG at the annual review.

The CAG noted that one lay representative would be added to the steering group and data release committee. Members asked if there were any plans to increase the lay representation.

The applicants advised that a parent representative had been added to the steering group. The applicant had also consulted the Leeds Young Research Owls, a group made up of 8–18-year-old children and young people who are passionate about being involved in and supporting research. The applicants are also working to establish a dedicated PPIE group, that includes male and female representatives of oncology, non-oncology and haemotology, parents and patients who have undertaken tissue storage. This will increase representation on the Steering Group and Data Release Committee and provide support for ongoing UKSTORE development work. The CAG noted this and raised no further queries.

11. **Please clarify on the long-term exit strategy, including whether the confidential patient information for deceased patients would be deleted once no further information could be collected.**

The applicants advised that updates to Core and Additional data will take place annually, until the tissue is used, no longer required, donated or destroyed, the patient dies, or storage limit is reached (whichever occurs first). For patients who have had tissue stored and are subsequently lost to follow up, Additionaldata will not be captured, but Core: basic and Core: enhanced data will be requested and retained. If patients die at any point, no further data capture will be performed, but data that has already been collected will be retained, including identifiers.

The applicants explained that the retention of identifiers was needed to allow use of UKSTORE data to undertake epidemiological and health services research requiring individual records of NHS activity to accurately examine preservation services usage, disease and treatment and describe late effects of diagnosis and fertility-impacting treatment. No being able to undertake these linkages would jeopardise the completion

and robustness of any UKSTORE Registry research work programme. Anonymised data would not provide a sufficient level of data quality to process and analyse each patient's care pathway and hospital activity accurately throughout their diagnosis, preservation, treatment and fertility journey. The CAG noted this and raised no further queries.

12. **Clarify who completes the dissent form, whether this is done by the patient or the treating clinician.**

The applicants advised that the primary purpose of the optout form is to record the level of opt-out requested by patients, as patients are given a choice on whether to withdraw all or part of their data. Patients are not asked to complete the form and it

will be completed by application staff. The CAG noted this 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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 20 September 2022**

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:**

   Due to the number of participating organisations involved, it is the responsibility of University of Leeds, as controller, to ensure that these participating organisations 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.

c. 22/CAG/0153 UK STORE - United Kingdom Register of Stored Ovarian and Testicular Tissue (Non-Research)

Name	**Capacity**
Ms Clare Sanderson	CAG Alternate Vice Chair
Dr Harvey Marcovitch	CAG Member
Mrs Diana Robbins	CAG Member

Mr Dan Roulstone	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

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The data will be obtained from all centres where ovarian and testicular tissue were collected and stored from patients aged 0-24 years. Storage centres will identify eligible patients via clinical records and local databases, and the confidential patient information transferred to UKSTORE. Confidential patient information will be used to perform data linkage to extract relevant data from existing databases. Additional data will be collected from patient medical records, directly from patients and from their GP's.

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follow up appointments will be sent an approved UKSTORE information sheet about additional data capture and invited to contact the tissue storage centre or UKSTORE directly, to give informed consent. This information will be sent alongside the next routine correspondence sent from tissue storage centres that confirms ongoing tissue storage. Storage centres will perform an additional safety check to screen and exclude patients they know have registered an opt out.

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	d. RTDS e. Hospital Episode Statistics (HES) admitted care f. National Disease Registration Service for patients with cancer, congenital anomalies and rare diseases (NCARDRS) g. National Cancer Registration Analysis Service (NCRAS) 5. GP data via GPES 6. External disease registries, including: a. The Welsh Cancer Intelligence & Surveillance Unit (WCISU) b. The European Society for Blood and Marrow Transplantation (EBMT) Registry. United Kingdom Primary Immunodeficiency (UKPID) Registry. c. The British Society for Paediatric and Adolescent Rheumatology (BSPAR). d. The National Haemoglobinopathy Registry (NHR).
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3. **Clarify why consent for core data could not be obtained at the same time as consent was obtained for additional data.**

The applicant advised that consent for additional data would also be sought once patients had reached the age of 18 years. Core data would be captured at the point of tissue harvest, which was most likely to occur between the ages of 0-16. Waiting

until all patients turn 16 to invite them to consent would create undue delay and result in an incomplete database unsuitable for robust research.

The CAG noted that this query may have been unclear. The CAG was not asking for patients to be consented at the time the core data was initially collected, but that the core data was originally collected under s251, and consent sought for the core data when patients were contacted for consent for the additional data. This would remove the reliance on support under s251 for the core data. Members requested further details on why it was not feasible to seek consent for the core data when contacting patients at age 18 for the additional data.

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If patients aged 16 or above give informed consent for capture of ‘Additional’ data, they will also receive information on ‘Core’ data capture, explaining how to opt-out if they wish. This approach will provide patients with a choice while also ensuring that UKSTORE can continue to understand how patients' needs change over time and the impact of tissue preservation on long-term clinical outcomes.

A consent model for ongoing data capture would require correspondences at multiple time points as patients turn 16, which would present an impossible administrative and financial burden to clinical services. Switching to a consent model for those patients who do give consent for ‘Additional’ data capture, whilst retaining reliance on section 251 for those who do not give consent, means maintaining two separate cohorts of patients which will inevitably create inefficiencies and complexities to manage the dataset effectively within a small resource with the additional risk that some data could be compromised within the register.

Furthermore, obtaining written informed consent for ‘Core’ data at the same time as consent for ‘Additional’ data may confuse patients and result in lower consent rates, negatively impacting the quality and completeness of UKSTORE data. For example, patients may not fully understand the difference between the two data sets or may feel overwhelmed by too much information at once. This is particularly relevant to patients who are not in regular follow up and whose priority is to receive direct clinical care when they re-engage with the clinical service. The CAG noted this and raised no further queries.

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The applicants advised that maintaining anonymised data on the entire population is vital to accurately report the impact of treatment and care on long-term outcomes for survivors. Patients were able to opt-out, but stated that retaining anonymised data was essential for the betterment of all children who store tissue. The CAG noted this and raised no further queries.

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The CAG agreed that it was not clear what patients needed to do if they did not want their data to be processed. The patient notification materials needed to be revised to contain a statement that patients can contact the registry directly and ask for their data to be removed. Members asked for confirmation that the website will contain the same statement about opt-out.

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The applicant advised that a lay representative will be included on both the steering group and data release committee. An update will be provided to the CAG at the annual review.

The CAG noted that one lay representative would be added to the steering group and data release committee. Members asked if there were any plans to increase the lay representation.

The applicants advised that a parent representative had been added to the steering group. The applicant had also consulted the Leeds Young Research Owls, a group made up of 8–18-year-old children and young people who are passionate about being involved in and supporting research. The applicants are also working to establish a dedicated PPIE group, that includes male and female representatives of oncology, non-oncology and haemotology, parents and patients who have undertaken tissue storage. This will increase representation on the Steering Group and Data Release Committee and provide support for ongoing UKSTORE development work. The CAG noted this and raised no further queries.

11. **Please clarify on the long-term exit strategy, including whether the confidential patient information for deceased patients would be deleted once no further information could be collected.**

The applicants advised that updates to Core and Additional data will take place annually, until the tissue is used, no longer required, donated or destroyed, the patient dies, or storage limit is reached (whichever occurs first). For patients who have had tissue stored and are subsequently lost to follow up, Additionaldata will not be captured, but Core: basic and Core: enhanced data will be requested and retained. If patients die at any point, no further data capture will be performed, but data that has already been collected will be retained, including identifiers.

The applicants explained that the retention of identifiers was needed to allow use of UKSTORE data to undertake epidemiological and health services research requiring individual records of NHS activity to accurately examine preservation services usage, disease and treatment and describe late effects of diagnosis and fertility-impacting treatment. No being able to undertake these linkages would jeopardise the completion

and robustness of any UKSTORE Registry research work programme. Anonymised data would not provide a sufficient level of data quality to process and analyse each patient's care pathway and hospital activity accurately throughout their diagnosis, preservation, treatment and fertility journey. The CAG noted this and raised no further queries.

12. **Clarify who completes the dissent form, whether this is done by the patient or the treating clinician.**

The applicants advised that the primary purpose of the optout form is to record the level of opt-out requested by patients, as patients are given a choice on whether to withdraw all or part of their data. Patients are not asked to complete the form and it will be completed by application staff. The CAG noted this 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 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

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 participating organisations involved, it is the responsibility of University of Leeds, as controller, to ensure that these participating organisations 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.

d. 23/CAG/0036 - Pre-clinical biomarker analyses for Gastrointestinal and Hepato-pancreatobiliary disease: cancers and inflammatory disorders

Name	Capacity
Professor William Bernal	CAG alternative vice-chair
Dr Malcolm Booth	CAG member
Ms Diana Robbins	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University of Nottingham set out the purpose of medical research which aims to investigate biomarkers using a variety of cancerous and inflammatory tissue of the gastrointestinal (GI) and hepato-pancreatobiliary (HPB) tract, to create prognostic, diagnostic, preventative, and predictive models to improve disease outcome and treatment. In the cancer research section, researchers will investigate a range of biomarkers within GI and HPB tumours and their metastases to facilitate diagnosis, prognosis, preventative measures and predictions to therapy. In the inflammatory disease section, researchers will investigate biomarker quality and expressions within GI and HPB inflammatory diseases that may be infective, metabolic, immunological, allergic or drug induced.

GI and HPB diseases, including inflammatory and malignant conditions with associated morbidity and mortality, are common, and cancer in general accounts for 166,533 deaths annually in the UK. There are a number of limitations to the current methods of histopathologic diagnosis. Consequently, the use of biomarkers has become a rapidly expanding field playing a central role in diagnosis and in the selection of tailored anti-cancer therapies. Furthermore, biomarkers are increasingly important to aid with screening, diagnosis, prognosis and predictions to therapy in disease. Hence, research into biomarkers for both cancer and inflammatory diseases is paramount to improve patient diagnosis and prognosis.

The project will use surplus tissue from retrospective diagnostic samples taken as part of standard of care, at Nottingham University Hospitals NHS Trust. Eligible patients will be identified the Data Management Team, who are not considered direct care team, hence the requirement for 's251' support. NHS Trust pathology computer systems will be searched to identify eligible participants, and linked to clinical data surrounding diagnosis from medical records. A pseudonymous ID is added, and confidential patient information removed by the Data Management Team. Subsequently, the tissue samples from identified participants will only be extracted by clinical colleagues (histopathologists at NUH). Therefore, this element does not require 's251' support.

A key between the pseudonymous ID and identifiable information will be retained within the Trust, by the direct care team, for 7 years after the study has ended as per standard procedure under the University of Nottingham sponsor arrangements. 's251' support is not required for this, as only direct care team will access the key. Only pseudonymous data will be provided to the research team at the University of Nottingham, who will not have the means to re-identify, and hence the data will be effectively anonymous. Tissue samples will be provided by the Department of Histopathology in Formalin Fixed Paraffin Embedded (FFPE) tissue blocks. The FFPE samples will have been taken during diagnostic surgical procedures and then prepared and stored under the local NHS procedures. Researchers will have access to the anonymised FFPE tissue and digital diagnostic images for analysis. Applicants may need to send anonymised material to different institutes outside of the UK, including Europe and the US for further analysis – this activity does not require 's251' support if appropriately anonymised in line with ICO code of practice, and the applicant has confirmed that this will be the case.

A recommendation for class 1 & 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	~5000 retrospective patients who have had a procedure to remove tissue from the GI or HPB tract at Nottingham

	University Hospitals, if there is surplus tissue available after diagnosis has been made. Tissue samples will have originally been taken from patients >5 years ago (between approximately 2000-2016). Microscopy image samples will have originally been taken from patients >1 year ago (between approximately 2000-2022).
Data sources	1. The Nottingham University Hospitals NHS Trust a. Histopathology samples/ Microscopy image samples b. histopathologic diagnosis from clinical records
Identifiers required for linkage purposes	1. NHS number 2. Hospital ID 3. Date of birth 4. Date of death
Identifiers required for analysis purposes	1. Gender 2. Ethnicity (this is effectively anonymous to the applicant)

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. **The poster should be revised in line with the advice in this letter, and an updated version provided to CAG. This should include;**
    a. **the title, and the subsequent text of the poster should be revised to be clearer and more accessible to the lay person.**
    b. **a more accurate representation of the length of time the key is retained for.**
    c. **The addition of a phone number and postal address for opt out.**

The applicant provided an updated document, which CAG initially requested changes to. The changes were made, and CAG were now content to support.

2. **Please provide more information about the patient and public involvement undertaken, specifically, if it addressed the use of confidential patient information without consent. Please provide any feedback form patients. If none has been undertaken surrounding this point, please undertake further patient and public involvement to cover this.**

The applicant confirmed that a patient and public involvement exercise was undertaken through Bowel Research UK PPI newsletter and a survey sent out. They have had very positive responses to the survey thus far from patients, carers and public; all respondents (24/24) have found the research extremely to very important; the majority (22/24) respondents thus far have indicated that they would not have any objection to the use of confidential material without consent. Applicants will be continuing our PPI through Bowel Research UK throughout this project. The CAG stated that this was sufficient to support.

3. **Please confirm whether it would be possible for the key between identifiers and pseudonym to be retained at the Trust by the direct care team only for the 7 year duration required, and thus remove the requirement for ongoing 's251' support.**

The applicant has confirmed that this would be possible, hence removing the requirement for ongoing support to retain the key.

4. **Please provide the Favourable opinion from a Research Ethics Committee, when available, as per standard condition of support below.**

This was provided as per 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 02 May 2023**

2. Confirmation provided from the DSPT Team at NHS England 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 England **21/22** DSPT review for **The Nottingham University Hospitals NHS Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 29 March 2023)

e. 22/CAG/0170 - Greater Manchester Care Record Research Database

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Mr Tony Kane	CAG member
Ms Diana Robbins	CAG member
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This research application submitted by NHS Greater Manchester Integrated Care, sets out the medical research purpose of creating a pseudonymised copy of the Greater Manchester Care Record (GMCR), to create an effectively anonymised research database, to facilitate research projects seeking to use routine data to address

important research questions about the health of the Greater Manchester population. Research undertaken using this database will include epidemiological (including Covid-19) studies, population health, and operational studies. Examples of previous research undertaken before the COPI notice expired includes trends in primary care-recorded self-harm during and beyond the Covid-19 pandemic, and ethnic inequalities in Covid-19 vaccination uptake. Examples of non covid-19 related research questions include investigating mental health outcomes for women and partners who have experienced pregnancy not ending in live births, and looking at 5 year survival after a diagnosis of dementia, and how it is affected by socioeconomic group.

In response to the Covid-19 pandemic, health and care organisations in Greater Manchester established the GMCR, a shared care record which amalgamates essential information for the city-region's 2.8m citizens from across health and care. This enables better informed direct care, digital transformation of care pathways, and was established for the purposes of direct care. This has been established since April 2020.

Under the Covid-19 COPI notice, the applicants data processor Graphnet created deidentified datasets for use for Covid-19 related population health research and other non-research secondary uses, also related to Covid-19. 15 university-led research studies have so far been approved looking at the impact of Covid-19 in Greater Manchester on cancer patients, mental health/self-harm, diabetes patients and the treatment of rheumatoid arthritis, amongst others. Some are still ongoing but are not currently processing identifiable informaiton and so do not require ‘s251’ support.

Applicants have confirmed that there has been no processing of the data for secondary uses between the expiry of the COPI notice (end of June 2022) and now. After the ‘s251’ support has been provided, the GMCR purposes are going to be wider than Covid-19 purposes.

This application for ‘s251’ support is to allow the disclosure of confidential patient information to Graphnet Health Ltd during the processing of the Greater Manchester Care Record, to create a pseudonymised dataset for research purposes. There is a sister non-research application for non-research secondary uses – **22/CAG/0169**. The De-identified data mart provides de-identified, linked row level data and is designed to be used for aggregate anonymised outputs for research purposes.

University of Manchester Research Data Engineers (RDEs) access the data mart via secure login and, for each research project, create a bespoke data extract that goes through several further rounds of de-identification. This data extract can be accessed via the data portal by named members of the group proposing the project. Data can only be downloaded from the portal in aggregate form once checked for disclosure control by a second project team member, and all downloads are monitored by Graphnet. RDEs and project team members cannot access the linkage key between the pseudonymised GMCR ID and confidential patient information.

Data access applications are restricted to research teams from UK HEIs only. The following restrictions will be applied for operations and capacity reasons:

- Undergraduate and master's students are not permitted to apply for data access
- PhD students registered at a Greater Manchester HEI may apply for data access
- PhD students from other UK HEIs may only apply for data access if the study is led by a Greater Manchester researcher who takes responsibility for the student's involvement

Study proposals must be approved by the GMCR Secondary Uses and Research Groups (SURG) before researchers are granted data access. The Research Operations Group (ROG) provides advice to the study team and assists them in progressing their proposal through the approvals process. Both groups will consider the following in their approval decision:

- Scientific robustness and relevance
- Data quality of the requested data
- Data minimisation principle
- Re-identification risks
- Completion of relevant data protection training by the applicants
- Relevant analysis expertise in the study team

GMCR Secondary Uses and Research Groups (SURG) contains lay representation, and CAG have been provided with their terms of reference. A list of all approved projects and any research outputs arising from the project is maintained, and more information on completed studies can be found at https://gmwearebettertogether.com/research-and-planning/

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	Approximately 3 million patients of all ages; (a) registered with a GP in Greater Manchester, or (b) have interacted with NHS services in Greater Manchester. This includes people that may have deceased since the GMCR was established. Records are not removed from the research database as they are needed for longitudinal research.
Data sources	1. Graphnet Ltd shared care records already linked together for purposes of clinical care, created from 500+ organisations including Primary Care, Secondary Care, Mental Health Trusts, Community Trusts, Out-of-Hours Services, Specialist Trusts, Social Care & North-West Ambulance Service, and local authorities
Identifiers required for linkage purposes	Graphnet will have access to the patient's entire medical record in the process of removing all items of confidential patient information
Identifiers required for analysis purposes	1. N/A – all analysis undertaken without the use of identifying information
Additional information	Approved researchers can access the data via a secure virtual environment provided by Graphnet.

	Source data is de-identified on a weekly basis – applicants have confirmed this has not happened since the expiry of the COPI notice.

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 clarify the proposed relationship with pharmaceutical companies, including whether any data is proposed to be shared under the 's251' support for this research database.**

The applicant confirmed that they will not share any data with pharmaceutical companies (or any industry partners) under this CAG application. Any future collaborations with pharmaceutical companies would be under a separate Analytics and Data Science Platform CAG application, as part of the Greater Manchester Secure Data Environment. The CAG were content with this response.

2. **Please provide further examples of research questions that you wish to answer using this research database.**

The applicant provided a list of 8 example questions, one of which is; *What is the patient journey for suspected gynaecological and skin cancers from primary to secondary care in Greater Manchester?.* The CAG were content with this response.

3. **Please provide clarity on if the dataset contains social care data, and if so, exactly what data is included. If it is included, please justify the need for it within this dataset.**

The applicant confirmed that they are excluding social care data at this stage. When any use cases that require social care data are identified, an amendment will be submitted. The CAG were content with this response.

4. **Please provide further information about how many lay individuals are in the GMCR Secondary Uses and Research Group (SURG), compared to other members.**

The applicant confirmed via a table, which showed 2 patient representatives compared to approximately 12 other expert members. The CAG were content with this response.

5. **Please provide an update terms of reference document for the SURG to include the assessment of medical purpose and public interest prior to agreeing ay data release.**

This was provided, and CAG were content.

6. **Please provide updated patient notification, which describes the breach of confidentiality for which 's251' support is requested, with a GMCR specific opt out option, split out into non-research and research.**

The initial documents provided did not provided an application specific opt out. After discussions with the applicant, in May 2023, updated notification documents were provided, after the applicant confirmed that they had developed a technical solution to allow an application specific opt out, over and above the National Data Opt Out and Type 1 opt outs. A poster and a patient notification document has been provided for review. The CAG thank the applicant for their efforts regarding this point. The CAG were broadly content with the notification documents provided, however recommended that a QR code that links to the website was added to the poster. This is ideal, but not mandatory, and can be provided to the Confidentiality Advice Team as a notification rather than a condition, or an amendment.

7. **Please detail the notification strategies that will be used to inform the patient population regarding this activity. This should include wider notification methods than only the website.**

The applicant responded to state that significant work went into communicating the development of the GM Care Record and privacy information to the public from Summer 2021 to Spring 2022, which included paid for advertising and communications toolkits for GM health and care organisations to use across their public facing channels. Elements of campaign will be repeated in Spring 2023, including using paid for

advertising on social media channels to communicate the privacy information and an updated communications toolkits for organisations to share with public including a leaflets and posters with privacy information to be sent to every GP practice in Greater Manchester. This method worked successfully before and utilises existing links across the GM Health and Care system to communicate messages to the public. The website will be comprehensively updated to highlight the latest privacy information and will be the focus for the public to find out about the GM Care Record and privacy arrangements. The CAG were content with this response.

8. **Undertake additional work with patients and the public to establish acceptability of the uses of data without consent, for the purposes of this application to CAG.**

The applicant responded to state that there are linked programmes of work, such as the development of a Secure Data Environment (SDE) in GM, where public engagement activity is planned, and applicants plan to build upon this planned activity to engage on the use of data without consent. This work will utilise existing links in seldom heard communities in Greater Manchester that were engaged with applicants as part of the communications campaign detailed previously. These existing groups (including the black African/Caribbean communities, South Asian communities, communities with high rates of deprivation and older age groups) will be revisited as part of the work on the SDE and the use of data without consent. In addition, Health Innovation Manchester, The University of Manchester and our other health and care partners have existing patient and public engagement groups that we will take this issue with to get their expert advice and views on.

The CAG noted the planned work, but as this was still in the planning stages, a condition was added for the applicant to provide a response within 6 months from the date of this letter, to provide feedback on patient and public involvement undertaken to establish the acceptability of the use of data without consent, for the purposes of this research application to CAG.

9. **Please provide a Favourable Opinion from the Research Ethics Committee as per standard condition of support.**

This was provided by the applicant as per 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. Please provide a detailed report at annual review, (or SDE application if before), to provide data on activities undertaken, which will be reviewed at a full CAG meeting.

2. Please provide feedback within 6 months from the date of this letter, on patient and public involvement undertaken to establish the acceptability of the use of data without consent, for the purposes of this research application to CAG.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 11 January 2023**

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:**

   The NHS Digital **21/22** DSPT review for **Graphnet Health ltd** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 02 December 2022)

f. 22/CAG/0169 - Greater Manchester Care Record – system supplier processing of confidential patient information to create a de-identified data mart for NHS GM secondary uses

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member

Mr Tony Kane	CAG member
Ms Diana Robbins	CAG member
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application submitted by NHS Greater Manchester Integrated Care, sets out the purpose of creating a pseudonymised copy of the Greater Manchester Care Record (GMCR), to be used for non-research secondary purposes such as population health management, and commissioning intelligence for example;

- Risk stratification,
- designing and targeting interventions to prevent ill health and improve care,
- reducing unwarranted variation in outcomes,
- reviewing service provision to identify gaps,
- strategic planning,
- redesigning care pathways,
- monitoring patient outcomes,
- Audits,
- Checking data quality,
- evaluating policy,
- improving patient safety

In response to the Covid-19 pandemic, health and care organisations in Greater Manchester established the GMCR, a shared care record which amalgamates essential information for the city-region's 2.8m citizens from across health and care. This enables better informed direct care, digital transformation of care pathways, and was established for the purposes of direct care. This has been established since April 2020.

Under the Covid-19 COPI notice, the applicant's data processor Graphnet created deidentified datasets for use for Covid-19 related population health research and other non-research secondary uses, also related to Covid-19. 15 university-led research studies have so far been approved looking at the impact of Covid-19 in Greater

Manchester on cancer patients, mental health/self-harm, diabetes patients and the treatment of rheumatoid arthritis, amongst others. Some are still ongoing but are not currently processing identifiable information and so do not require 's251' support.

Applicants have confirmed that there has been no processing of the data for secondary uses between the expiry of the COPI notice (end of June 2022) and now. After the 's251' support has been provided, the GMCR purposes are going to be wider than Covid-19 purposes.

This application for 's251' support is to allow the disclosure of confidential patient information to Graphnet Health Ltd during the processing of the GMCR, to create a pseudonymised dataset for non-research secondary purposes. There is a sister research application for research uses – 22/CAG/0170. The de-identified data mart provides de-identified, linked row level data and is designed to be used for aggregate anonymised outputs such as population health, public health, risk stratification and segmentation. Access to the de-identified data mart will be made available to NHS GM ICS partners under an application and GM governance approval process as set out in the DPIA.

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	Approximately 3 million patients of all ages; (a) registered with a GP in Greater Manchester, or (b) have interacted with NHS services in Greater Manchester. This includes people that may have deceased since the GMCR was established. Records are not removed from

	the research database as they are needed for longitudinal analysis.
Data sources	1. Graphnet Ltd shared care records already linked together for purposes of clinical care, created from 500+ organisations including Primary Care, Secondary Care, Mental Health Trusts, Community Trusts, Out-of-Hours Services, Specialist Trusts, Social Care & North-West Ambulance Service, and local authorities.
Identifiers required for linkage purposes	Graphnet will have access to the patient's entire medical record in the process of removing all items of confidential patient information
Identifiers required for analysis purposes	1. N/A – all analysis undertaken without the use of identifying information
Additional information	Source data is de-identified on a weekly basis – applicants have confirmed this has not happened since the expiry of the COPI notice.

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. **Define what the applicants consider to be risk stratification and population health activities, with examples of each, noting this will be used to define the scope of the application.**

The applicant explained that population health is a strategic aim for Integrated Care Systems (ICSs); to improve physical and mental health outcomes, promote wellbeing and reduce health inequalities across an entire population. Population Health

Management (PHM) is a data driven approach to help commissioners and frontline teams understand current health and care needs and predict what local people will need in the future. This means applicants can tailor better care and support for individuals, design more joined-up and sustainable health and care services and make better use of public resources.

To do this, applicants need to link health care datasets together (e.g., hospital and GP data) at a patient level to create a holistic view of population need and service utilisation. It will also allow applicants to understand the effectiveness of health care provision for population groups. The linked datasets will allow development of a range of products. Some examples include:

• **Neighbourhood and population cohort profiles**: interactive dashboards that describe the demographic profile of a population (e.g., age, ethnicity, people with learning disabilities or multiple long-term conditions etc) and analyse their usage of existing services in comparison to other population groups. These profiles will support service re-design and tackle health inequalities.

• **COVID and Flu Vaccination Dashboard:** interactive dashboards split by location and population groups e.g., protected characteristics to support the planning of vaccination programmes and monitor their take up. For example, does the analysis show a need to put in place specific services to improve take up for specific population groups?

• **Targeted Lung Health Checks:** interactive dashboard to support the planning. delivery and evaluation of a targeted lung health check programme

• **Long Term Conditions (LTC) Dashboards:** e.g., dashboards used by Primary Care Networks (PCNs) and GPs to plan and deliver their LTC management programmes. The dashboards will include case finding, patient management and outcome monitoring functionality.

Regarding risk stratification, applicants will link hospital (SUS) and GP datasets together to develop risk stratification dashboards that will be used by clinicians to identify at risk patients and offer then a suitable intervention. Some examples include:

• **Risk of emergency admission:** applicants identify patients at risk of emergency admission and the Case Management Service pro-actively puts care plans in place to prevent re-admission and reduce length of stay in hospital

• **Cardio-Vascular Risk Dashboard**: PCNs and GP Practices will make use of a dashboard to put preventative interventions in place for patients at risk of developing CVD

• **Elective Recovery Programme:** applicants will link the waiting list and GP data together to segment and put measures in place to support vulnerable patients who are waiting for treatment e.g., patients with multiple long-term conditions.

The CAG were content with this response.

2. **Provide clarity whether the dataset contains social care data, and if so, what type of social care data is included, and justify why it is needed.**

The applicant confirmed that they are excluding social care data at this stage. When any use cases that require social care data are identified, an amendment will be submitted. The CAG were content with this response.

3. **Please provide updated patient notification, which describes the breach of confidentiality for which 's251' support is requested, with a GMCR specific opt out option, split out into non-research and research.**

The initial documents provided did not provided an application specific opt out. After discussions with the applicant, in May 2023, updated notification documents were provided, after the applicant confirmed that they had developed a technical solution to allow an application specific opt out, over and above the National Data Opt Out and Type 1 opt outs. A poster and a patient notification document has been provided for review. The CAG thank the applicant for their efforts regarding this point. The CAG were broadly content with the notification documents provided, however recommended that a QR code that links to the website was added to the poster. This is ideal, but not mandatory, and can be provided to the Confidentiality Advice Team as a notification rather than a condition, or an amendment.

4. **Please detail the notification strategies that will be used to inform the patient population regarding this activity. This should include wider notification methods than only the website.**

The applicant responded to state that significant work went into communicating the development of the GM Care Record and privacy information to the public from Summer 2021 to Spring 2022, which included paid for advertising and communications toolkits for GM health and care organisations to use across their public facing channels. Elements of campaign will be repeated in Spring 2023, including using paid for advertising on social media channels to communicate the privacy information and an updated communications toolkits for organisations to share with public including a leaflets and posters with privacy information to be sent to every GP practice in Greater Manchester. This method worked successfully before and utilises existing links across the GM Health and Care system to communicate messages to the public. The website will be comprehensively updated to highlight the latest privacy information and will be the focus for the public to find out about the GM Care Record and privacy arrangements. The CAG were content with this response.

5. **Undertake additional work with patients and the public to establish acceptability of the use of data without consent, for the purposes of this application to CAG. A report of this work should be provided to CAG.**

The applicant responded to state that there are linked programmes of work, such as the development of a Secure Data Environment (SDE) in GM, where public engagement activity is planned, and applicants plan to build upon this planned activity to engage on the use of data without consent. This work will utilise existing links in seldom heard communities in Greater Manchester that were engaged with applicants as part of the communications campaign detailed previously. These existing groups (including the black African/Caribbean communities, South Asian communities, communities with high rates of deprivation and older age groups) will be revisited as part of the work on the SDE and the use of data without consent. In addition, Health Innovation Manchester, The University of Manchester and our other health and care partners have existing patient and public engagement groups that applicants will take up this issue with to get their expert advice and views on.

The CAG noted the planned work, but as this was still in the planning stages, a condition was added for the applicant to provide a response within 6 months from the date of this letter, to provide feedback on patient and public involvement undertaken to establish the acceptability of the use of data without consent, for the purposes of this non-research application to 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 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. Please provide a detailed report at annual review (or with a future SDE application if earlier), to provide data on non-research activities undertaken, which will be reviewed at a full CAG meeting.

2. Please provide feedback within 6 months from the date of this letter, on patient and public involvement undertaken to establish the acceptability of the use of data without consent, for the purposes of this non-research application to CAG.

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 **21/22** DSPT review for **Graphnet Health ltd** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 02 December 2022)

2. New Amendments

18/CAG/0064 – National Bone and Joint Infection Registry

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

Context

Amendment request

This application is the national registry for Bone and Joint Infections in the United Kingdom, which is used for audit and service evaluation purposes.

This amendment sought support for the National Bone and Joint Infection Registry to include private practices in addition to NHS Trusts, in order to receive data regarding patients treated within a private healthcare setting (providers within the Private Healthcare Information Network – PHIN). The amendment is requested due to the increasing numbers of patients across the UK who are undergoing trauma and orthopaedic surgery in private institutions, including for bone and joint infection. Therefore, in order to accurately audit care and provide useful feedback on available data, it is essential that the audit includes information for patients undergoing management of their bone and joint infection in a private setting to the registry. In particular, given the complex and varying nature of bone and joint infection management there may be multiple patient flows between private and NHS care that would otherwise not be identified. The amendment is therefore requested to ensure that the audit is able to provide accurate data analysis with a subsequent impact on understanding of best practice care for this patient group, as outlined in the aims of the registry.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair was content to recommend support to include the private sector, noting that this would include a significant proportion of joint replacement and revisions.

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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

The NHS England **21/22** DSPT reviews for **Dendrite Clinical Systems & Northumbria Healthcare NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 21 April 2023)

22/CAG/0130 – ELUCIDate: ELUcidate long-term consequences of Childhood Infections using administrative and research Data

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study aims to investigate the health consequences of SARS-CoV-2 infection in children and young people (CYP) using two school surveys: the Schools Infection Survey (SIS) in England, and the Bristol-based COVID-19 Mapping and Mitigation in Schools (CoMMinS) study.

This amendment sought support to include an additional purpose for processing; the applicants will now be including a related research question, *"Do children and adolescents experience long-term health outcomes of (any) infection, and how is this characterized?*" using acute fever (as reported in SIS) as a marker for infection, and compare with long-term outcomes from SARS-CoV-2. This is because it is crucial to understand whether post-COVID syndrome is distinguishable from the long-term effects possible from a host of other infections.

This amendment also sought support to change the name of the application from: '*Enhancing The Utilisation Of COVID-19 Testing In Schools Studies: The Joint Analysis Of The COVID-19 Schools Infection Survey (SIS) And The COVID-19 Mapping And Mitigation In Schools (CoMMinS) Study'* to an umbrella term – '*ELUCIDate: ELUcidate long-term consequences of Childhood Infections using administrative and research Data'*, to cover all of the additional purposes.

This amendment also notified the CAG of additional funding - Dr Katharine Looker has received additional funding in the form of an NIHR Advanced Fellowship, and a grant for the analyses specified in the original application has also been secured from the NIHR School of Primary Care Research. This is noted as for notification only.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment, noting it was no more disclosive than the original application.

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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed:**

   The NHS England 21/22 DSPT reviews for **NHS Digital, and the Office of National Statistics** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 16 March 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 9 May 2023**

CAG 5-07(f)/2013 – National Vascular Registry

Name	Capacity
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The National Vascular Registry (NVR) is commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England and the Welsh Government, as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). In the previous NVR contract (which covered 2018-2022), NHS England and HQIP were the joint data controllers for the English NVR data, and the Welsh Government and HQIP were the joint data controllers for the Welsh NVR data. The Royal College of Surgeons of England (RCSEng) were the data processors. An amendment was supported in January 2020 for NVR to collect data on medical devices implanted during a repair of an abdominal aortic aneurysm.

The collection of this device data has been excluded from the 2023-2025 specification for the NVR, and thus the contract between the RCS and HQIP which began on 1st January 2023. However, NHS England have instructed the RCSEng to continue to collect English data on devices from 1st January 2023 under a separate agreement. This change means HQIP will no longer be one of the data controllers of the device data collected within the NVR. Nonetheless, NHS England, the Welsh Government and HQIP will remain the joint data controllers of the rest of the patient data collected within the NVR. The RCSEng will remain the data processors of all of the data collected within the NVR (including the device data). There will be no change to the data items being collected or the flow of patient data from NHS hospitals to the NVR from 1 January 2023, and Regulation 5 support is already in place for the collection of this data.

The regulation of implantable devices and the need to monitor the performance and safety of these medical devices nationally is increasingly recognised, not least because a few endovascular devices for abdominal aortic aneurysms (AAA) have been reported to have comparatively poor longer term outcomes. Without this continued support, the

NVR would not be able to monitor and report on the long term outcomes of implanted vascular devices. Information on these outcomes is not currently collected by any other central organisation.

Therefore this amendment sought support for a change in data controllership regarding only data on medical devices implanted during a repair of an abdominal aortic aneurysm, collected into NVR. From 1st January 2023, HQIP will no longer be a joint data controller, and NHS England will be data controller for English data and the Welsh Government will be data controller for Welsh data, with regards to data on medical devices implanted during a repair of an abdominal aortic aneurysm, collected into NVR.

Patient information materials have been updated to reflect the change in data controller for the device data on the NVR.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. The amendment was submitted after discussion with CAT, and no further queries were raised regarding this administrative 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:** The NHS England **21/22** DSPT review for **The Royal College of Surgeons of England** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 28 March 2023)

20/CAG/0133 – Yorkshire Specialist Register of Cancer in Children and Young People (YSRCCYP)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

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 England (previously 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 include Patient Reported Outcome Measures (PROMs) as an additional data source, from Leeds Teaching Hospital NHS Trust (LTHT). PROMs data alongside NHS number and/or hospital case number will be disclosed from the LTHT Trust to YSRCCYP, initially on a retrospective basis for patients already included in the register. For prospectively registered patients, LTHT will disclose PROMS data to YSRCCYP subsequently, once the patient's core dataset is registered. YSRCCYP will then link the self-reported PROMs data relating to the quality of life, psychological wellbeing, patient-reported symptoms, social wellbeing and functional status of patients to the existing YSRCCYP dataset. This will enable applicants to investigate the impact of these reported outcomes on survival and other disease outcomes (e.g. relapse, subsequent cancer/treatment) in the patient population. Applicants will also investigate variations in PROMs according to socioeconomic and ethnic differences. A revised data flow diagram has been submitted to reflect this new data source.

This amendment also sought support to change the research database hosting environment for YSRCCYP from University of Leeds-LASER, to AIMES, therefore include a new data processor for this application. This change is to be implemented to provide a more effective database infrastructure for both data collection and processing. There is no change to the Data Controller (University of Leeds). The applicant confirmed that the transfer of data between the systems would be gradual, and therefore security assurances are required for both University of Leeds–LASER and AIMES until the transfer is complete. Once the transfer is complete, no security assurances will be required for the University of Leeds, as despite people employed by the University working on the YSRCCYP, the YSRCCYP data itself will be held and

processed entirely within AIMES, and the University of Leeds as a legal entity will not be processing any confidential patient information.

The applicant has also informed CAG about updated patient notification documents, which have been accepted as notifications to CAG, and about plans for patient and public engagement (which are outside of scope of 's251' support required).

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT). CAT clarified the security assurance requirements with the applicant, and raised no further queries regarding this 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed:**

   The NHS England **21/22** DSPT submissions for **University of Leeds – Laser, and AIMES were confirmed as 'Standards Met' by NHS Digital (by check of DSPT tracker on 04 May 2023).**

   Security assurances are required for the organisations 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 University of Leeds, as data controller, to ensure that appropriate security assurances are in place. This includes NHS England (previously NHS Digital), EMIS,

TPP, Department for Education and Department for Work and Pensions, and participating NHS Trusts.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 27 April 2023

21/CAG/0007 – National Neonatal Audit Programme (NNAP) data flow

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

Context

Amendment request

The applicants have existing support for the disclosure of confidential patient information contained in the BadgerNet system, for Clevermed Ltd to extract confidential patient information in a dataset and further disclosure to the RCPCH Azure hosting infrastructure.

This amendment informs CAG that under Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002, a new flow of data from the National Neonatal Audit Programme (NNAP) will be disclosed to the UK Health Security Agency (UKHSA). This is out of scope of Regulation 5 support, and this CAG amendment. The UKHSA run the Infection in Critical Care Quality Improvement Programme (ICCQIP), and will use the data on neonatal unit patients to improve surveillance coverage of bloodstream infection occurring in neonatal units, since currently only around 7% of neonatal units submit data to the ICCQIP. The data obtained from the NNAP will also permit additional analyses to provide greater understanding of bloodstream infection and their management by neonatal units.

UKHSA will link the NNAP data with Second Generation Surveillance System (SGSS) infection data. There will then be a flow of linked pseudonymised data back to NNAP, for the purposes of linking back to the main NNAP dataset. NNAP have the ability to re-identify, and therefore this flow, although pseudonymous, requires a legal basis under common law. This amendment sought support for this flow to come under Regulation 5, as the purposes of this flow fulfils the audit purposes of NNAP. The NNAP will use the linked data to continue to report against the NNAP bloodstream infection metric, via existing quarterly and annual mechanisms. This amendment is therefore for the addition of a new data source (SGSS), data processor (UKHSA), and data flow (one way from UKHSA to NNAP), noting that although Regulation 3 will cover the flow of confidential patient information to UKHSA, regulation 5 support is needed for the provision of data back to NNAP for NNAPs purposes.

Confidentiality Advisory Group advice
The amendment requested was considered by Chairs' Action. The Chair was content to support this 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed:**

   The NHS England **21/22** DSPT reviews for Royal College of Paediatrics & Child Health, Clevermed Ltd, and UKHSA were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 11 May 2023).

22/CAG/0051 – Our Future Health

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Professor Lorna Fraser	CAG Member
Dr Pauline Lyseight-Jones	CAG Member
Mr Andrew Melville	CAG Member
Ms Rose Payne	CAG Member
Dr Murat Soncul	CAG Alternate vice-chair
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from Our Future Health Ltd aims to create a research tissue bank for early detection of disease. It aims to speed up the discovery of new methods of early disease detection, and the evaluation of new diagnostic tools, to help identify and treat diseases early and anticipates that this will lead to better patient outcomes. The applicants have Regulation 5 support to allow the disclosure of confidential patient information from NHS England (previously NHS Digital) to APS Group, the contracted mailing supplier, to facilitate the sending of invitation letters to selected patients. The initial outcome provided support for approximately 3 million patients to be contacted, with previous amendments supported to increase the number of patients to 16 million. However, an amendment to increase the number to 45 million was deferred due to the significant increase without tangible evidence of the additional benefits and sufficient considerations of practical alternatives.

This amendment sought support for an additional 8 million patients to be contacted, over approximately 6 months, to make a total of 24 million people, with an expected further amendment to be submitted at 3 months for a further 8 million, to make a total of 32 million people. This is due to the increased capacity of both clinic availability, and

invitation mailouts. This means individuals can be invited at a higher rate, and greater scale to support achieving recruitment targets.

Confidentiality Advisory Group advice

The amendment request was considered at a Sub-Committee meeting of the CAG on 05 May 2023.

With regards to the original application, the CAG were supportive in principle of this research application, however, significant concerns were raised by CAG regarding the rapid increase on reliance of Regulation 5 support, from 3 million approximately 1 year ago, to approximately 24 million requested in this amendment. It was noted by Members that there was always an intention to increase the number of invites sent from the initial 3 million, and the scientific justification for consenting 5 million people has already accepted by REC, and this is not increasing. However, Members are aware that the proposed use of confidential patient information without consent to support recruitment is on a vastly greater scale and needs careful consideration as to whether there is a additional public interest.

Public interest

CAG has a responsibility to justify that there is sufficient public interest in any recommendation of Regulation 5 support, balancing the anticipated benefits against the use of confidential patient information without consent, including its scale. To support this consideration, CAG requested some examples of tangible benefits of the end results of Our Future Health.

The applicants summarised the expected benefits specific to those who consent to Our Future Health. This consisted of immediate benefits (for example blood pressure and cholesterol check) and medium-term benefits (provision of integrated risk score on request). Whilst CAG accepted this was a direct benefit to those consenting it is not sufficient to justify the scale of use of confidential patient information to aid recruitment.

Regarding wider benefits to the population Our Future Health indicated that they hope to accept data access request in Autumn 2023. The more rapidly a cohort of significant size can be created, the sooner researchers can begin to use the resource to discover,

test, validate and implement new ways of detecting, intervening and treating common chronic diseases. Whilst CAG noted the desire to recruit quickly it does not justify the large scale use of confidential patient information without considering other recruitment methods and the efficiency of this recruitment route (see below).

If the cohort can be recruited quickly the applicant stated that as the number of episodes of a condition increase, earlier detection, and earlier treatment of disease begin to accrue, there is an overall benefit to both individuals, society, and the health system from reduced co-morbidity and impact of disease. Further the applicant anticipated benefits of a large longitudinal cohort will be of particular benefit for rare diseases, in identifying individuals at high or low risk for certain diseases, stratifying health screening by risk and identify pre-disease biomarkers.

Whilst the Committee understand that a degree of this is speculative, it was felt that the applicants had still not defined with clarity, what the actual expected medical benefit to the public would be. The CAG requested specific examples of potential studies that could be undertaken, and specific examples of what sort of questions Our Future Health is expected to be able to answer, to provide CAG with examples of a tangible benefit to the public.

CAG stated that achieving any benefit outlined requires a cohort to be established. Our Future Heath stated aim is to recruit 5 million people. However, whilst the vast majority of participants so far have been recruited through Digitrials, the response rate through this method is low. Given this, even if 45 million people were invited through this route CAG noted that Our Future Health would be substantially short of its stated aim.

The applicants explained the efforts being made to adapt the letters to optimise recruitment. However, CAG were concerned that this alone is unlikely to achieve the target, and to reach this, other recruitment methods that do not require Regulation 5 support must be used and optimised, and may be practicable alternatives to support.

Given the concern in reaching the 5 million target, CAG requested further information on the minimum number of consented that will achieve anticipated benefits. The group were uncomfortable supporting such a large-scale use of confidential patient information without consent if it was impossible to provide a benefit to the public because the recruitment target could not be reached. Our Future Health remains

committed to the 5 million target. However, some of the stated benefits of the Our Future Health Programme can be realised with smaller sample sizes, but to truly make discoveries and help improve healthcare across the whole population, Our Future Health will require the 5 million sample size.

The CAG were unclear from these responses if there was a minimum number of consented patients that will still yield a public benefit, and asked the applicant to clarify. The applicant responded that there would be a public benefit from 1 million consented individuals upwards, stating this would be the absolute minimum target. The applicant added that recruiting 3, 4 or 5 million patients would see increasing benefits when it came to rare diseases. The CAG accepted this explanation and felt that this strengthened the requirement for the applicant to better explore practicable alternatives, and to take time to improve the conversion rate.

Given the importance of establishing a cohort, members were concerned that the pace of the recruitment appeared rushed and, because of this, it was not possible for the applicant to work to maximise recruitment, by properly reviewing feedback, undertaking continuous patient and public involvement, and to get the maximum benefit from patient notification. The applicants stated that the longer recruitment took the longer it will be for benefits to be realised, a justification that members felt was insufficient to justify the support requested in the amendment.

Whilst noting the applicant's assertion that pausing recruitment through Digitrials would be very damaging to recruitment, the CAG felt that a sufficient public interest argument had not been given by Our Future Health. Mindful of the financial commitments already made in the short term planning, Members agreed to support a further increase of 4 million invites, to a total of 20 million. However, the CAG was concerned that the applicants have yet to demonstrate a strong public interest for sending invites above 20 million and would be less supportive of any further increases without substantial work to demonstrate this additional level of public benefit.

Members strongly advised Our Future Health to slow the pace of recruitment to ensure adequate time is dedicated to understanding how recruitment rates through Digitrials can be significantly improved, how other routes or recruitment (see below) can be employed, how the public can be involved to influence this (see below) and how the public can be better informed (see below) to increase participation.

Any future amendment should make reference to specific examples of work expected to be undertaken with the dataset, to better demonstrate the public interest of continuing to use confidential patient information without consent to recruitment people to Our Future Health. It should also detail the steps Our Future health have taken to reflect on current recruitment in order to both improve the recruitment rate through Digitrials, and the use of other methods. Tangible evidence of an improvement of the response rate (estimated to be up to 8% by September), and consent rate should also be submitted with any future amendment.

Practicable alternatives

Members were aware that other methods of recruitment were described in the original application, which are outside of CAG remit. The initial CAG application planned for only 150,000 individuals out of 5 million to be consented via the DigitTrials recruitment method. As part of the deferred amendment, CAG requested an appraisal of all recruitment routes being used, in order to evidence if these alternative methods could represent a practicable alternative to the requested amendment to Regulation 5 support.

Given it is likely that Our Future Health will wish to invite all adults in England via Digitrials, it was unclear to Members as to why the electoral roll could not be used to send invites as a practicable alternative, as this would not require the use of confidential patient information without consent. The applicants stated that the rationale of use of the electoral roll is unhelpful as it is harder to target underrepresented populations (a key target for Our Future Health) and could potentially result in sending an invite to those that have already received one. The CAG commented that it was hard to justify the Digitrials recruitment method as superior in targeting underrepresented groups when the applicant ultimately wished to invite every adult in England, and that the data available to Digitrials does not allow for screening in sufficient demographic detail to ensure that underrepresented groups can be identified.

The applicants also commented that recruitment from NHS Blood and Transplant will start at the beginning of July, with the aim to consent about 500,000 patients using this method. Our Future Health are in early stage discussions with NHS England and the Department of Health and Social Care with regarding recruitment through the NHS health check programme. Recruitment in Wales, Scotland and Northern Ireland is also planned. The applicants also describe using iPLATO to send SMS invitations to patients across 120 GP practices who have consented for data to be used in this way. Boots

chemist also sent invitations to advantage card holders, and there are plans to also use a customer distribution list from Pharmacy2U. All these methods were practical alternatives to support through Regulation 5.

The Committee requested the applicant make every effort to maximise recruitment from these other methods, requesting ongoing updates regarding all other methods of recruitment, and should undertake further patient and public involvement as described below, in order to help reach underrepresented and hard to reach groups.

Patient notification and media campaigns

As a response to the deferred amendment, the applicant provided evidence of how the media campaigns are working, and indicated that the focus of these adverts is partly to ensure the Digitrials methodology has an opt out option prior sending of invites. The applicants indicate that no further increase in patient notification was necessary given that advertising has been running every month since July 2022 and the volume of opt-outs has not increased in line with the increase in campaign activity/visibility.

Whilst CAG accepted this justification, it was thought however that much more emphasis should be given to using media campaigns as an aid to recruitment as well. Members felt the campaigns should focus on the benefits that Our Future Health can bring in order to increase awareness and gain the interest of the population in participation. This focus will support the recruitment campaigns both by Digitrials and other methods.

Any future amendment should detail the work undertaken by Our Future Health to review and improve the communications to the population. Given the emphasis to increase recruitment in underrepresented groups it was unclear to members what work has been undertaken with these communities to see how campaigns can be targeted to improve recruitment. This should also be detailed in any future amendment.

Patient and Public Involvement

Despite the patient and public involvement undertaken in targeting hard to reach groups as part of the initial application, it appeared from the information provided to CAG in the deferred amendment, that no further patient and public involvement had been undertaken since 2021 relating specifically to the sharing of confidential patient information without consent in order to send out invitation letters, and it did not appear that any patient and public involvement had been undertaken specifically surrounding the increasing of invitations via NHS DigiTrials. The applicant was advised to undertake further patient and public involvement prior to this current resubmission.

The applicants conducted a survey with 15 members of their Public Advisory Board, the Ethics Advisory Board and the Equality Diversity and Inclusion Board. Two questions were asked on whether the benefits of increasing the volume of invitations (to 45million) outweighed the risks and whether the respondent is comfortable with this. Both answers reported 66% agreed and 34% either disagreed or were neutral. Comments from respondents have been provided, but there is no indication if there is any further analysis or changes planned in response to these comments.

CAG did not consider that a sample size of 15 people drawn from those already on an Our Future Health Board is sufficiently representative of the potential cohort of 45 million people. It was also noted that 34% of these people were not supportive of the increase in invites via Digitrials, and that, despite wishing to include underrepresented and hard to reach groups, this does not seem to be reflected in the patient and public involvement undertaken.

The CAG felt that significant further work is necessary in this area. More emphasis is required on patient and public involvement with representative (underrepresented and hard to reach) groups, with more granularity and detail as to exactly what the public feel about the specific aspects of the increase in the cohort size and data use without consent. The CAG considered that very considerable patient and public involvement should be undertaken in geographical areas where OFH have already sent invites, including those who had consented to Our Future Health in order to gain feedback around the consenting process. Patient and public involvement should also be undertaken in areas where OFH are planning to recruit. This patient and public involvement could also be used to ask people how best to communicate with the public, in order to try to maximise the consent rate, the content of the invitations, and any actions after an invitation has been sent. The Committee commented that this should be undertaken in a few areas, and with at least 50 individuals from each geographical area. The groups should be diverse and representative of the local cohort being targeted. Details of questions asked should be provided, alongside responses. The CAG wish to understand what the public feel about this increase of invitations, in order

to help balance the breach of confidence as compared to the public benefit resulting from the project.

Future amendments

The CAG consider that Our Future Health should take time to consider and action the above conditions. The committee is not prepared to consider any further amendments to increase the number of invites, until the end of September 2023. If the responses to these conditions as part of any future amendment are insufficient, the amendment is unlikely to be supported.

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 only to support a small continuation of this amendment, and therefore advised recommending conditional support to the Health Research Authority. The Members were in favour of recommending support for a smaller increase in Digitrial letters than requested. CAG required the applicants to undertake the work described above, analyse the new data, review how alternative recruitment plans could be most effective and develop a plan which would maximise recruitment that did not require Regulation 5 support and minimise the recruitment via Digitrials and Regulation 5 supported methods.

Health Research Authority decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The amendment, to allow an additional approximate 8 million patients to be contacted for consent, over approximately 6 months, to make a total of approximately 24 million people (increased from 16 million), is **not supported.**

2. The amendment, to allow an additional approximate 4 million patients to be contacted for consent, over approximately 6 months, to make a total of approximately 20 million people (increased from 16 million), **is supported**, subject to compliance with the standard and specific conditions of support.

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

   The NHS England **2021/22** DSPT review for **APS Group Ltd** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 17 February 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed on 22 February 2023 that this is covered as part of REC Favourable Opinion provided on 23 May 2022 (AM03 – protocol update)**

3. To support a future amendment (after end of September 2023) for any further invites to be sent, the below points should be taken into consideration. A detailed covering letter should be provided to support any future amendment submission, which addresses the below points and sets out where revisions have been made.

   a. Please provide specific examples of research that could be undertaken, and examples of what sort of questions Our Future Health is expected to be able to answer, to provide CAG with examples of a tangible benefit to patients, the public, and the NHS.

   b. Please provide clear evidence of both the response rate to Digitrials invitations, (expected to be at least 8% in the next 4 months) and also of the conversion rate between people expressing their interest in taking part, and going on to consent, and how these have been increased.

   c. Please make efforts to maximise recruitment from other methods that do not use confidential patient information without consent, and provide ongoing updates regarding improvements in all other methods of recruitment for any future amendment.

   d. Whilst the stated intent is to reach underrepresented and hard to reach groups, CAG were unconvinced the current actions achieve this – please provide further evidence of why Digitrials is the only way this can be achieved.

e. Please consider and report to CAG on the effectiveness of the media campaigns to gain the interest of the population, and any changes that have been made as a result.

f. Please undertake patient and public involvement in both areas that had received a letter and areas that had yet to, of a scale proportionate to the disclosure – a minimum of 50 participants in each group. These groups should be diverse and representative of underrepresented and hard to reach groups. Provide a clear report on how this was undertaken, details of questions asked, and responses, what the outcomes were, what concerns were detailed, and how OFH have considered changes to act on any concerns raised.

18/CAG/0159 – Housing, family and environmental risk factors for hospital admissions in children

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to investigate the impact of environment and socio-economic factors on hospital admissions in children. The project uses an established birth cohort of infants born in England between 2005 and 2014. This is linked to 2011 Census Data and small area level data on air pollution and building characteristics in order to create a dataset to facilitate analysis. There have been many amendments to this initial 's251' support.

The applicant has 's251' support in place regarding receiving postcodes from the Personal demographics service (PDS) at NHS England, for the purposes of linkage to air pollution and buildings data, and to health data in the birth cohort to be able to examine respiratory health risks of air pollution and buildings exposures in children. An amendment was also supported 24 November 2020 to allow access to postcodes at delivery from the ONS birth registration records in the SRS in order to link to LSOA level variables on multiple deprivation.

This amendment seeks support for the applicant to use the delivery postcodes from birth registration data to compare against the PDS postcodes for mothers and babies, thereby validating the linkage. In cases where applicants deem the PDS postcodes to be unreliable, the applicant seeks support to link the air pollution, tobacco expenditure and buildings data to the ONS birth registration postcodes and use these for analyses instead. All these data are already held in the ONS SRS, and no further data transfers are required. Once applicants have validated the postcode linkage fully, and derived air pollution and building exposure variables, ONS will restrict access within the SRS to the postcode variable on the birth registration data again.

In addition, in the original 's251' support, it is mentioned that applicants will be linking the mother baby cohort to daily air pollution data at 100x100m grids for the years 2010-2012; in fact applicants were able to obtain these data for the years 2010-2014 from Cambridge Environmental Research Consultants, who do the air pollution modelling. Whilst this does not affect the linkage or use of personal identifiable information, it is a change to the original protocol, and so this amendment is to clarify the air pollution data year span.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. No queries were raised regarding this 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

   The NHS England 21/22 DSPT reviews for **the Office for National Statistics, University College London – School of Life and Medical**

Sciences & NHS Digital were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 March 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 05 May 2023

22/CAG/0165 – Shaping care home COVID-19 testing policy: A pragmatic cluster randomised controlled trial of an intervention to promote regular, asymptomatic testing in care home staff: VIVALDI-CT

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application is investigating the feasibility, effectiveness and cost-effectiveness of regularly testing care home staff for COVID-19 to protect residents from severe infection and prevent outbreaks. 's251' support is currently in place for the disclosure of confidential patient information (regarding residents admitted to hospital) from care homes to NHS England, for the purposes of linkage to the NHSE Foundry (COVID-19 datastore) (which will then be pseudonymised and disclosed to UCL).

This amendment sought support to include additional participating care home providers as additional data processors for the application;

- Glentworth House Nursing Home - 40-42 Pembroke Ave, Hove, BN3 5DB
- Read House - 23 Esplanade, Frinton-on-Sea CO13 9AU
- Alexander Care Home - 164 Rochdale Road, Bury, BL9 7BY
- Chandos Lodge Nursing Home - Blackpond Ln, Slough SL2 3ED
- Cantelowes House - 27 Cantelowes House, Spring Close, Barnet, EN5 2UR
- Bings Hall - Chelmsford Road, Felsted, Dunmow, CM6 3EP
- Coxbench Hall - Alfreton Rd, Coxbench, Derby DE21 5BB

- Glow Rest Home - 58 Villiers Avenue, Surbiton KT5 8BD
- Andrew Cohen House - River Brook Dr, Stirchley, Birmingham B30 2SH

The justification for this amendment is to ensure that the research question is able to be answered, as more sites are required in order to do so.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed:**

The NHS England **21/22** DSPT review for **NHS England** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 24 May 2023)

Due to the number of organisations involved it is the responsibility of University College London, as controller, to ensure that participating organisations 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.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 02 May 2023

16/CAG/0066 – Hospital Alerting Via Electronic Noticeboard (HAVEN)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from Oxford University Hospitals NHS Foundation Trust aims to produce a hospital-wide IT system that enables a continuous risk assessment in all hospital patients, and predicts those at risk of deterioration. Support is currently in place to cover the disclosure of confidential patient information from participating Trusts to the HAVEN research team at the Critical Care Research Group, Nuffield Department of Clinical Neurosciences, University of Oxford.

The database contains detailed diagnostic coding, event timing and full date of death. Full date of death constitutes confidential patient information, and therefore 's251' support will be required until full date of death is deleted. Removing these data will significantly impact the usefulness of the data for ongoing analysis into improving the early detection of patients.

Therefore this amendment sought support to extend the duration of 's251' support until 31 March 2026.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

   The NHS England 21/22 DSPT review for **Critical Care Research Group, Nuffield Department of Clinical Neurosciences, University of Oxford (EE133863-NDCN-CCRG)** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 24 May 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 08 March 2023**

18/CAG/0038 – A randomised controlled trial to evaluate invitation to community-based low dose computed tomography (LDCT) screening for lung cancer versus usual care in a targeted population at risk.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the Leeds Teaching Hospitals NHS Trust aims to test targeted Low Dose Computed Tomography (LDCT) scans screening in community settings concentrating on deprived areas of Leeds. The intention is to randomise 55-80 year old

smokers or ex-smokers to intervention or usual care groups prior to approach. The intervention group will be invited to an assessment for a Lung Health Check (including LDCT screening for high-risk people) framed as a pilot health service.

Amendments were supported on 4 January 2022 and 17 November 2022 to change data flows on advice from NHS Digital (now NHS England).

On discussion with Advisory Group for Data (AGD), in relation to NHS England as the trusted third party, the applicant is seeking support in this amendment to change the dataflows, as AGD consider there is a practicable alternative to NHS England (previously NHS Digital) undertaking the linkage in the design initially proposed, and have asked the applicant to undertake the linkage within the YLST eCRF and database. This amendment therefore also sought support to remove NHS England (previously NHS Digital) as a data processor for the application.

The new data flows requiring ‘s251’ support are as follows;

1. Reed Wellbeing Ltd (processor for One You Leeds) would disclose confidential patient information (name, address, date of birth, gender and a OYL unique ID) about the OYL cohort to the YLST Data Scientist at Leeds teaching Hospital NHS Trust.

2. The YLST Data Scientist will download the supplied confidential patient information to Leeds teaching Hospital NHS Trust secure network, and use name, address and gender to identify the NHS Number.

3. The YLST Data Scientist would disclose confidential patient information (NHS Number and OYL unique ID) from Leeds teaching Hospital NHS Trust to the University of Leeds, where linkage with the YLST cohort would take place in the Leeds Institute for Data Analytics Virtual Research Environment (LIDA VRE).

4. University of Leeds would disclose confidential patient information (OYL unique ID for matched participants) back to Reed Wellbeing Ltd (processor for One You Leeds), in order for them to link back to the required clinical fields, and provide the required information back to University of Leeds (also via the OYL unique ID).

This data will be analysed on the University of Leeds VRE by the YLST statistician.

Confidentiality Advisory Group advice
The amendment was considered by the Confidentiality Advice Team, who raised no queries regarding this 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 DSPT team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed**

   Leeds Teaching Hospitals NHS Trust, University of Leeds – LASER, CFH Docmail LTD, and Reed Wellbeing Ltd, and NHS Digital have confirmed 'Standards Met' on DSPT 21/22 (by check of DSPT tracker 24 May 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee; **Confirmed 10 May 2023**

20/CAG/0001 – Functional outcomes In Trauma (FIT) Study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Leeds aims to assess the impact of major trauma, especially polytrauma, on the physical aspect of functional outcome and how this changes over time.

This amendment sought support to extend the duration of the 's251' support until 1 October 2026, to allow the applicant to complete the study.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

   The NHS England 21/22 DSPT review for **University of Leeds and Leeds Teaching Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 24 May 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 10 May 2023**

18/CAG/0126 – Connected Health Cities: Data linkage of urgent care data

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to create a research database, in which routine NHS data from a number of providers of emergency and urgent care (EUC) in the Yorkshire and Humber region is collected and linked to provide a coherent picture of EUC demand in the region.

The original data linkage has been completed, however the applicants are now seeking support to delay the deletion of the patient identifiers until 30 December 2025, which will allow them to complete the further data linkages, for which a separate new CAG application has been already supported (22/CAG/0019).

REC favorable opinion has been renewed for the CUREd data base until June 2028 and the reference number is 23/YH/0079. The new IRAS reference is 325288. These references have been updated with regards to this CAG letter.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT), who raised no queries regarding this 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

   The NHS England **21/22** DSPT reviews for **Sheffield Teaching Hospitals NHS Foundation Trust**, and **University of Sheffield School of Health and Related Research** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 24 May 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 25 April 2023**

22/CAG/0021 – The South London Stroke Register: Improving the lives of stroke survivors with data. (SLSR)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has 's251' support to allow members of the SLSR research team from King's College London, who are not considered part of the direct care team, to view confidential patient information whilst screening for eligibility, inviting patients to consent, and extracting an anonymous dataset for analysis regarding deceased patients, at Guy's and St Thomas' NHS Foundation Trust and King's College Hospital NHS Foundation Trust.

This amendment sought support for a change to Chief Investigator. Dr Iain Marshall will replace Professor Charles Wolfe as Chief Investigator, who will continue as a co-investigator. The name of the Chief Investigator has been changed where it appears - GP notification letter, PIS (aphasia) and Protocol.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

   The NHS England 21/22 DSPT reviews for **Guy's and St Thomas' NHS Foundation Trust (RJ1) and King's College Hospital NHS Foundation Trust (RJZ)** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 25 May 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 26 April 2023**

21/CAG/0089 – Evaluating the integration of the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) into primary care and its impact on patient treatment and care

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to evaluate the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) process for adults in primary care, to determine how, when and why it is used, and what effect it has on patient treatment and care. The application has 's251' support to allow (as part of Work packages 1 & 3) the research team, who are not considered members of the direct care team, to view confidential patient information while extracting a pseudonymised set of demographic data from GP records, and care homes. The applicants anticipated that this will often be done by members of the direct care team, however support is in place should this not be possible.

This amendment sought support to extend the duration of 's251' support until 31 July 2023, to allow the feasibility study to be completed.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed:**

Due to the number of participating care providers involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information 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 care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 05 April 2023

21/CAG/0126 – A retrospective cohort study to investigate body composition and survival in metastatic breast cancer

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has ‘s251’ support to allow the disclosure of confidential patient information at University Hospital Southampton NHS Foundation Trust in order for researchers who are not part of the direct care team to screen medical records for eligibility and extract a pseudonymised dataset for analysis.

This amendment sought support to extend the duration of ‘251’ support until October 2024, to enable the applicant to complete the study.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries as part of this 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

   The NHS England 21/22 DSPT review for **University Hospitals Southampton NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 24 May 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 24 May 2023**

22/CAG/0131 – STandardising pAthways for diagnosing hypeRtension using routine healLthcare data: an InvestiGation of the Health and economic ouTcomes: STARLIGHT, Version 1.0

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has 's251' support to allow the disclosure of confidential patient information from Oxford-Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID) Database (at University of Oxford (Nuffield Department of Primary Care Health Sciences)) to Oxford University Hospitals NHS Foundation Trust

to allow linkage, and disclosure of an effectively anonymous dataset to the applicants at University of Oxford.

Applicants have identified a lower risk, more efficient method of data linkage which involves the transfer of less patient data. The original data flow for STARLIGHT was for the hashing algorithm used to pseudonymise ORCHID data to be transferred from Oxford University to OUHNHSFT to allow OUHNHSFT to hash the NHS IDs for patients in their dataset in the same way; Oxford University would then have transferred the ORCHID pseudonymised dataset for the eligible cohort to OUHNHSFT, who would add patient data for the same cohort to create the linked, amalgamated dataset. This linked dataset would then have been transferred back to Oxford University for analysis by the study team.

This amendment sought support for an updated data flow. The new proposed method of linkage retains the first step, in which the hashing algorithm used by ORCHID to hash NHS IDs for patients within their dataset is transferred from Oxford University to OUHNHSFT to allow OUHNHSFT to hash the NHS IDs for patients in their dataset in the same way. Rather than Oxford University then transferring the pseudonymised ORCHID dataset for the eligible cohort to OUHNHSFT, applicants now propose that Oxford University transfers only the hashed NHS IDs for the eligible cohort, without any healthcare data. This will allow OUNHSFT to identify the patients in their dataset who are eligible for inclusion in the study, without having access to any additional patient data. OUHNHSFT will then transfer pseudonymised data for the eligible cohort to Oxford University, who will then add the ORCHID data for the eligible patients to create the linked, amalgamated dataset. This will reduce the amount of personal data being transferred, as only data from one data source will be transferred rather than data from two data sources. ‘s251’ support is required for this linkage, as despite being transferred in pseudonymous format, both parties have access to the hashing algorithm and can re-identify.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who noted this was less disclosive than the original design.

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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

   The NHS England 21/22 DSPT reviews for **University of Oxford (Nuffield Department of Primary Care Health Sciences) - EE133863-MSD-NDPCHS (regarding ORCHID) and Oxford University Hospitals' NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 24 May 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 19 May 2023**

19/CAG/0001 – National Respiratory Audit Programme (NRAP): children and young people asthma audit (CYPA)

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

Context

Amendment request

This application from the Royal College of Physicians on behalf of the Healthcare Quality Improvement Partnership (HQIP), is regarding the Paediatric Asthma Clinical Audit. The audit is commissioned as part of the National Asthma and COPD Audit Programme (NACAP).

From 1 June 2023, National Asthma and COPD Audit Programme (NACAP) will be called the National Respiratory Audit Programme (NRAP). The Royal College of Physicians (RCP) were commissioned to deliver NACAP until 31 May 2023. The RCP were successful in being awarded the new HQIP contract to deliver the children and young people asthma audit (CYPA) as part of the National Respiratory Audit Programme (NRAP), commencing 01 June 2023. All current NACAP secondary care clinical audits, COPD, adult asthma, children and young people asthma and pulmonary rehabilitation, as well as the Wales primary care audit, will continue under NRAP. This amendment therefore sought support to change the name of the audit from ***'****National Asthma and COPD Audit Programme (NACAP): Paediatric Asthma Clinical Audit'* to *'National Respiratory Audit Programme (NRAP): children and young people asthma audit (CYPA)'.*

Support is currently in place to cover the collection of audit data for all admissions of children and young people to hospital with asthma attacks (ages 1-18) in England and Wales, on a continuous basis.

This amendment sought support to include further diagnoses as part of the inclusion criteria, (for age 1-5) of ICD 10 codes: 'B34.9 – Viral infection (primary diagnosis) AND R06.2 – Wheezing (secondary diagnosis) AND any of the asthma codes listed as a third diagnosis', to ensure the audit captures all relevant cases. The changes are also detailed below;

Include patients:

- who are between 1 and 5 years old on the date of arrival and have been admitted to a hospital paediatric service with:
    - a primary diagnosis of an asthma attack
    - or a primary diagnosis of wheeze AND a secondary diagnosis of asthma
    - OR a primary diagnosis of viral infection AND a secondary diagnosis of wheeze AND a tertiary diagnosis of an asthma attack (include patients where this was initially unclear, but later identified as an asthma attack/wheeze AND asthma attack)

This amendment also sought support for additional data items to be collected as part of the audit, including ethnicity, and mental health status – consisting of a yes/no answer, and then a diagnosis drop down. The applicant seeks to collect these data items to ensure the audit can report on these data, to try to reduce health inequalities.

This amendment does not seek to change the data flows or confidential patient information collected. No additional direct patient identifiers beyond what has already been agreed will be collected for the children and young people asthma audit (CYPA).

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs Action. The Chair was content to recommend support for the amendment, to collect additional data items which will help to improve the health inequalities arising from these conditions.

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. Support under this application extends to the non-research audit purposes only. There is no support in place for the processing of information collected within the audit for research purposes.

2. Confirmation provided from the DSPT team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

   The NHS England 21/22 DSPT reviews for **Royal College of Physicians, Crown Informatics Limited, Imperial College London, Aimes Management Services & NHS Digital** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 12 May 2023)

   The Welsh IG team have confirmed security assurances are in place for DHCW.

15/CAG/0134 – The risk of major bleeding with novel anti-platelets: A comparison of ticagrelor with clopidogrel in a real world population of patients treated for acute coronary syndrome

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application is a study of patients who have been treated for Acute Coronary Syndrome (ACS) with either ticagrelor or clopidogrel and corresponding patient bleeding. Liverpool University Hospitals NHS Foundation Trust has undertaken a medical note review regarding the last 2500 patients who received clopidogrel for ACS as a new prescription prior to a change in guidelines, and also on the last 2500 patients receiving ticagrelor patients. Identifiable data is retained, under 's251', and linkage has already been undertaken with Hospital Episode Statistics (HES) and other clinical outcomes including mortality, locally.

This amendment sought support to change the wording of the research question From: *'comparing the efficacy and risk of major bleeding of ticagrelor and clopidogrel therapy in a real-world population of patients treated for acute coronary syndrome'*, To: '*validating metrics that are used to calculate the bleeding vs reinfarction risk when placing patients on anti-platelet medications (such as ticagrelor and clopidogrel)'*. Providing comprehensive validation of clinical decision making tools, regarding the decision to place patients on antiplatelet therapy to stop subsequent heart attacks, would give clinicians confidence to use them, enabling the correct selection of patients for antiplatelet therapy; minimising both occurrences of bleeding and further heart attacks. The applicant intends to evaluate CRUSADE, Precise-DAPT, ACUITY and ARC-HBR.

The amendment also sought support to undertake a further linkage with Hospital Episode Statistics (HES), to include six additional data points on the existing cohort - history of previous bleeding, history of liver cirrhosis, history of a coagulopathy, history of cancer, history of recent surgery or trauma, and history of thrombocytopenia. In order to do this, the applicant will disclose NHS numbers and date of birth to NHS England.

The amendment also sought support to disclose a pseudonymised dataset to Liverpool heart and Chest hospital (LHCH) for analysis. The pseudonymised analysed data will be returned to Liverpool University Hospitals NHS Foundation Trust, upon which the data held at Liverpool Heart and Chest Hospital will be destroyed. No 's251' support is

required for this flow, as the statistician will not have the means to re-identify the patients. However the additional disclosure is noted.

In this amendment, the applicant clarified also that Aintree University Hospital and The Royal Liverpool Hospital Trusts have now merged to form Liverpool University Hospitals NHS Foundation Trust (LUHFT).

The applicant also sought support to extend the duration of ‘s251’ support until January 2024.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold: **Confirmed:**

   The NHS England **21/22** DSPT reviews for **Liverpool University Hospitals NHS Foundation Trust & NHS Digital** were confirmed as ‘**Standards Met’** on the NHS England DSPT Tracker (checked 24 May 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 10 May 2023**

3. Annual Review Approvals

CAG reference	Application Title
21/CAG/0156	Understanding SARS-CoV-2 infection, immunity and its duration in care home staff and residents in the UK (VIVALDI STUDY)
17/CAG/0115	ECG Diabetic Foot Ulcer (DFU) Pilot
ECC 5-05 (j)/2012	Long term risk of cervical cancer following a HPV infection
21/CAG/0094	Time limited access for NHS Digital to undertake record linkage of East Anglian Air Ambulance patients to HES and ECDS
17/CAG/0073	Application to hold patient identifiable data within the National Head and Neck Cancer Audit (HANA)
22/CAG/0065	Comorbidities and outcomes of patients with chronic pancreatitis: a single centre cohort study
18/CAG/0056	Retinoblastoma gene mutations and risk of second primary tumours
15/CAG/0119	MBRRACE-UK – Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP)
21/CAG/0050	Suicide in former service personnel: rates, antecedents, and prevention
21/CAG/0061	British Paediatric Surveillance Study of Neonatal Stroke in the United Kingdom and the Republic of Ireland presenting/diagnosed in babies in the first 90 days of life.
PIAG 2-07(b)/2004	The Oxford Monitoring System for Attempted Suicide
22/CAG/0118	NICOR - Extended Use of Data V1.1 2017
ECC 8-04 (b)/2013	Road Accident In-Depth Studies (RAIDS)

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Murat Soncul & Professor William Bernal, CAG Alternate Vice-Chairs	*13 June 2023*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*06 June 2023*