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

November 2023

Please note, these minutes contain varying formats, as we work through a change of process regarding CAG outcomes.

1. New Applications

a. 23/CAG0155 - CAG Overarching Application for Oxford Vaccine Group (OVG) Studies

Name	Capacity
Dr Martin Andrew	Expert Member
Dr Malcolm Booth	Expert Member
Dr Tony Calland MBE	Chair
Dr Harvey Marcovitch	Expert Member
Dr Stephen Mullin	Expert Member
Ms Rose Payne	Lay Member
Mr Dan Roulstone	Lay Member
Ms Clare Sanderson	Alternate Vice Chair

Dr Murat Soncul	Alternate Vice Chair
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from the University of Oxford set out the purpose of recruitment of patients to vaccine clinical trials.

The Oxford Vaccine Group (OVG), based in the Department of Paediatrics at the University of Oxford, conducts studies of new and improved vaccines for children and adults. It conducts a range of clinical trials on the basis of consent each with relevant approvals from the MHRA and REC. Previously, a range of recruitment methods have been used but because the number of studies has increased the applicants wish to undertake a range of identification and recruitment procedures.

This application, specifically for the vaccine trials below, requests support to allow NHS England to search for eligible patients within specific postcodes surrounding the Oxford area (where the trial centre is based). This extract of name, address and postcode will be transferred to PSL Print Management Ltd to send invitations. Oxford Vaccines Group will not receive any confidential patient information until the patient proactively contacts them if interested in a particular study, at which point all activities operate under consent. Patients will be sent no more than 3 mailouts in any given year, with at least a three-month period between mailouts.

Trials included in this support outcome

- Development of a Live Attenuated Vaccine against Salmonella Paratyphi A (VASP) IRAS Project ID: 249094 REC: 21/SC/0330
- A single-blind, randomised, phase II multi-centre study to determine reactogenicity and immunogenicity of heterologous prime/boost COVID-19 vaccine schedules in adolescents (COMCOV-3) IRAS Project ID: 304450 REC: 21/SC/0310
- A phase I study to determine the safety and immunogenicity of a new vaccine against Middle East Respiratory Syndrome Coronavirus in Adults aged 50 to 70 (MERS) IRAS Project ID: 1006223 REC: 23/SC/0047
- A phase 1 safety and immunogenicity study of a Crimean-Congo haemorrhagic fever virus vaccine, ChAdOx2 CCHF, in healthy adult volunteers in the UK (CCHF) IRAS Project ID: 1007128 REC: 23/LO/0420
- An open label Phase I/IIa clinical trial to assess the safety, immunogenicity and efficacy of the malaria vaccine candidate RH5.2-virus-like particle (VLP) in Matrix-MTM, and to compare the safety and immunogenicity of the malaria vaccine candidates RH5.2-VLP in Matrix-MTM and RH5.1 soluble protein in

Matrix-MTM used in various regimens (BIO-001) IRAS Project ID: 1005729 REC: 23/LO/0412

- Phase I clinical trial to assess the safety and immunogenicity of the malaria vaccine candidate RH5.1 soluble protein in Matrix-MTM using two dosing regimens (BIO-002) IRAS Project ID: 1005754 REC: 23/LO/0058
- Heterologous Boosting for Hexavalent Paediatric Vaccines in the UK Schedule (6in1 Part 2) IRAS Project ID: 1006942 REC:23/EE/0121

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 meeting the broad inclusion criteria for the above studies.
Data sources	1. The Personal Demographics Service (PDS) held by NHS England 2.
Identifiers required for linkage purposes	1. Date of birth 2. Postcode
Identifiers required for analysis purposes	1. Name 2. Address 3. Postcode
Additional information	Date of birth is used to ensure eligibility and are not transferred to PSL Print Management Ltd. No identifiers are sent to Oxford Vaccines Group. They will not have any contact until a patient proactively approaches them interested in a trial.

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.

Provide a report on the patient and public involvement undertaken to date specifically on the recruitment via NHS England route, and the acceptability of the use of confidential patient information without consent. This should include the patient and public involvement undertaken on each study listed on the initial application, plus the broader work undertaken on 2 October 2023.

For each piece of patient and public involvement detail should be provided on:

- **the number of participants**
- **demographics of the participants**
- **what format the involvement took (e.g. focus group, survey)**
- **summary of the discussions and comments made by the participants.**

For the 2 October 2023 event, please also provide any content (e.g. slides, information sheets) that was presented to the applicants to describe the use of confidential patient information without consent and what was asked to the participants. Where concerns were raised, the report should detail any actions taken to mitigate those concerns.

The applicants provided a full description of the 2 October event, including the demographics, number of attendees and the topics covered. Slides from the event were also provided. The response included the concerns or suggestions made, and the actions undertaken to mitigate such concerns. Overall however there was broad agreement that the use of Confidential Patient Information without consent by NHS England to support the recruitment was justified.

CAG were content with the response provided though reinforced the need to continue this with the general public in areas close to currently known trial sites, as set out in the conditions.

Provide a broad plan for ongoing patient and public involvement on the recruitment method and the acceptability of using confidential patient information without consent. The plan should include details on

- **how the recruitment method will be tested in general with the patient and public involvement group, and frequency of such testing**
- **how involvement will be undertaken for future specific studies with the Oxford Vaccines Group Patient and public involvement group**
- **how involvement will be undertaken with the wider public in geographical areas close to each trial site.**

Plans should align with HRA principles and should include testing the acceptability of using Confidential Patient Information without consent, as per CAG principles.

The applicants commented that for each new vaccine trial their standing patient and public involvement group will be engaged to discuss recruitment methods and the acceptability of the use of Confidential Patient Information without consent by NHS England to support the recruitment will be discussed. It is expected that this group will be expanded in size to cover wider geographical areas. In addition, the applicants will use the NIHR ‘road ‘test’ programme which involves Research Champion public volunteers meeting with study teams to ‘road test’ all aspects of the study including review of study materials and recruitment methods.

CAG were content with the response.

As per previous precedents with similar applications, the following line should be added to the patient invitation letter, specifically in the section on "*Accessing data for research mailouts*", "[*For NHS database extracts include:]*".

"*NHS England holds information from the records that health and social care providers in England keep about the care and treatment they give. The data they hold can be used to plan and improve health services, including medical research*."

The applicants provided an updated invitation letter including the suggested text.

CAG were content the response had been satisfactorily answered.

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. For the current eight vaccine trials listed within the initial application, undertake patient and public involvement within areas local to the currently known trial sites, and outside of the Oxford Vaccines Group patient and public involvement group. A report on these trial sites should be provided at first annual review.
2. Future vaccine trials from Oxford Vaccines Group should be submitted as an amendment before Section 251 support is confirmed. Each amendment submitted to CAG to add a new vaccine trial should include the following:
    a. Completed CAG amendment form.
    b. Supporting document that provides:
        i. A summary of the vaccine trial (as per the lay summary of the study provided to REC and MHRA as part of the combined review form).
        ii. A description of the cohort to be included in the trial.
        iii. The target number of participants to be recruited.

iv. An estimated number of letters to be mailed through NHS England/ PSL Print Management Ltd.

v. Information as to whether this is a single site (in Oxford) or multi-site vaccine trial.

vi. A summary of why this recruitment method is necessary for this application.

vii. A summary of the study specific patient and public involvement within the area local to sites (including numbers, format of event, what was presented and asked of attendees and summary of comments).

3. Before any future amendment for new vaccine trials, the applicants should consider the necessity of using this recruitment approach and why other less disclosive approaches alone are not viable.

4. For future vaccines trials which use new trial sites to Condition 1, undertake patient and public involvement within these local areas and provide a report with the amendment to add the trial.

5. Notify CAG when a vaccine trial completes recruitment and therefore is no longer reliant on Section 251 support.

6. Annual reviews will be considered at a full meeting of the CAG.

7. Favourable opinion from a Research Ethics Committee. **Confirmed**

8. 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:**

    a. The NHS England 22/23 DSPT review for NHS England and PSL Print Management Ltd were confirmed as 'Standards Met' on the NHS England DSPT Tracker.

b.

23/CAG/0090	**King's College London Cardiovascular Diseases Database**
Chief Investigator:	**Dr Nilesh Pareek**
Sponsor:	**King's College Hospital NHS Trust**
Application type:	**Research Database**

Present:

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice Chair
Mr Thomas Boby	CAG Member (Expert)
Dr Malcolm Booth	CAG Member (Expert)
Dr Pauline Lyseight-Jones	CAG Member (Lay)

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

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

Summary of application

This application from King's College Hospital NHS Trust set out the purpose of medical research, of aiming to create a research database collecting data on all patients admitted with cardiovascular disease (CVD), or seen in cardiology outpatient clinic at King's College Hospital NHS Trust (KCH) and Guy's & St Thomas' NHS Trust (GStT). The database aims to advance prevention, early diagnosis and treatment of cardiovascular disease in the locality, and will support research into 4 cardiovascular disease research themes; acute & chronic coronary syndromes, structural and valvular heart disease, arrhythmia and complex electrophysiology, and heart failure & cardiomyopathy.

Structured and unstructured data collected during routine delivery of cardiology care will be extracted from electronic patient notes (EHR) by machine-learning artificial intelligence software (Cogstack), into 2 site-specific research databases: King's Electronic Records Research Interface (KERRI), and Guy's & St Thomas' Electronic Records Research Interface (GERRI). This will involve free text data such as patient appointment systems, pathology results, imaging and diagnostics, and letters and scanned documents for the purposes of research. The data will be extracted and structured to facilitate analysis and research. The applicant is not requesting 's251' support for this process. During the extraction process, identifiable information will be removed from the clinical datasets (i.e, name, hospital and NHS ID) or weakened (i.e., date of birth and address). However NHS number and full date of birth will still be retained in 2 separate files at each Trust, alongside assigned registry specific IDs, to create the GStT and KCH linkage files held separate from the pseudonymised clinical data. The GStT Linkage File and the pseudonymised GStT clinical data file are both transferred to KCH, and the GStT linkage file will be linked to the KCH linkage file, for

the purposes of de-duplication, and to create a single KCL-CVD Registry Linkage File (containing identifiers), that is accessible only to CI & database manager. Pseudonymised clinical data from KCH is then combined with clinical data from GStT in a single pseudonymised KCL-CVD Disease Registry retained by KCH.

The KCL-CVD Registry Linkage File containing NHS number, full Date of Birth, and registry ID is shared with NHS England to enable linkage with Hospital Episode Statistics (HES) & ONS Mortality Data. NHS England will disclose a dataset back to the applicant containing full date of death amongst other outcome data. The data will be linked to the clinical data within the registry, and the full date of death will then be modified for analysis. After completion of the database, it will be stored for 10 years.

Researchers who have a substantive contract with KCH or GStT, or a substantive contract with KCL and honorary contract with KCH/GStT, will be able to request datasets for specific research questions. All proposed research projects require approval by an Oversight Committee. The Oversight Committee will review the proposal in respect to the scientific validity, the skill-mix of the research team, the potential benefit to patients and the risk for potential patient reidentification. At present, there are no plans for a lay person to sit on the Oversight Committee, however the Oversight Committee will meet on a six-monthly basis with the PPI Oversight Group to review research priorities and ongoing governance. If approval is issued, the researchers will receive the minimal required dataset for their analysis. Data will remain within the Trust firewall at all times and can only be removed in the form of graphs and scientific reports.

Confidential information requested

Cohort	All patients admitted with cardiovascular disease (CVD), or seen in cardiology outpatient clinic at KCH or GSsT, between April 2012 to March 2022 Approximately 150,000 individuals
Data sources	1. Participating Trusts Electronic patient Records; • King's College Hospital NHS Trust (KCH) • Guy's & St Thomas' NHS Trust (GStT) 2. NHS England: • Hospital Episode statistics • ONS mortality data
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Registry specific ID
Identifiers required for analysis purposes	1. Date of death – received form NHS England, and modified for analysis 2. Month and year of birth

	3. Sector level postcode in order to calculate deprivation score 4. Gender 5. Ethnicity 6. Registry specific ID
Additional information	Linkage file with NHS number, D.o.B. & Registry ID held separately from the pseudonymised clinical data, that is only accessible to the applicant and the Clinical Informatics lead, who share leadership of the resource. KCL-CVD Registry Database locked following NHS England linkage – the linkage key to NHS number is deleted after 5 years.

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

#	**Action required**	**Response from the applicant**
1.	Continued ongoing PPI is to be undertaken, and the applicant should provide an overall plan to CAG regarding ongoing PPI.	**Plan for ongoing PPI**: · Lay member will join the Project Committee (meeting frequency of monthly to quarterly depending on volume of applications for datasets) · 6 monthly meeting of PPI Oversight Group · PPI Oversight group will require a minimum of 5 members · 6monthly 'campaigns' where members of public and patients will be approached on hospital premises by members of research team (i.e., in outpatient clinic waiting rooms, investigation waiting rooms, cardiac daycare ward, and cardiac in-patient wards) to complete 'structured interviews' using an updated questionnaire (231018.PPI Questionnaire v1.2 – attached.) · A QR link has been added to updated poster and patient information

		leaflet (Version 1.3) that can allow members of public or patient body to access and complete a questionnaire via online survey · The Registry Protocol (231016.Protocol v1.3) has been updated to highlight the importance of ongoing PPI to guide the evolution of the project The CAG were content with this response.
2.	The ongoing PPI should specifically focus on the use of confidential patient information without consent.	· The Template PPI Questionnaire has been updated accordingly, with Section b dedicated to *'Use of Confidential Data in Research without Individual Patient Consent'* (231018.PPI Questionnaire v1.2 – attached.) The CAG accepted this response, however a condition has been applied for the applicant to provide updated information to CAG, which shows how many people respond to the questionnaire, such as a summary of issues/concerns raised or whether people are generally supportive, within one month.
3.	The ongoing PPI should be undertaken with considerably more individuals, and should include a more diverse mix of individuals.	· The applicant notes that they share this goal and acknowledge the value of involving a more diverse mix of individuals · Applicants expect that the addition of the 6 monthly PPI 'campaigns' and availability of QR code on promotional material will allow them to reach a larger and more diverse mix of people. The CAG were content with this response.
4.	The CAG requested that there be lay membership on the Oversight	· A lay member will join the Project Committee

	Committee (which assesses data access requests).	· The lay member will be nominated by the PPI Oversight Group · Ideally, the nominated person would also be a member of the PPI Oversight Group (but this is not a mandatory prerequisite for them to join the Project Committee) The CAG accepted this response, but noted that the Terms or Reference stated that the Oversight Committee needs 3 members to attend in order to be quorate. It appears that these 3 need not include the lay member. The CAG requested that lay membership be part of the quorum requirements.
5.	Provide terms of reference for the Oversight Committee, and confirmation of how applications' intentions to use the data are reviewed with regards to public benefit and medical purpose.	· Completed and Provided '231018.KCL-CVD Committee Terms of Reference.v.1.0' The CAG accepted the Terms or reference were now updated as requested.
6.	Provide updated patient notification materials, which are written in lay language which is more accessible to the lay reader.	· Updated Patient Information leaflet and Poster (version 1.3, dated 18 October 2023) The CAG accepted this response.
7.	The updated patient notification materials should be clearer about the role of CAG and 'section 251' being the common law legal basis for the application.	· Updated Patient Information leaflet and Poster (version 1.3, dated 18 October 2023) The CAG accepted this response.
8.	The updated patient notification materials should be clearer about use of confidential patient	· Updated Patient Information leaflet and Poster (version 1.3, dated 18 October 2023) The CAG accepted this response.

	information being used for the purposes of linkage.	
9.	The updated notification should remove the link to the NDOO. The application specific opt out option should be described first on the notification document, and then merely state that the NDOO will be respected if one has been registered.	· Updated Patient Information leaflet and Poster (version 1.3, dated 18 October 2023) The CAG accepted this response regarding the updated wording on the notification leaflet, however noted that the poster has not been updated to align. The CAG request that the applicant revise the NDOO section on the poster to state they will respect any choice they have previously made through the National Data Opt-out, in a similar manner to the leaflet.
10.	Provide the draft website text.	· This will be the text included in the poster with links to the comprehensive Patient Information Leaflet and online PPI survey The CAG accepted this response.
11.	Clarify why key is to be retained for 5 years.	· It is a key priority of our project that data should be used in a manner that minimises risk of re-identification, whilst maximising the value and insights derived from it · We believe keeping the key for 5 years helps to maintain this balance · Initially the key will be used to validate the accuracy of the data-linkage through limited sampling · The initial linkage with NHS Hospital Episode Statistics and ONS Mortality Data will provide a comprehensive dataset on health outcomes for our cohort, but maintaining the key (for a limited period) will allow the possibility to perform linkages to other external datasets if further important research questions arise (subject to requisite approvals) The CAG accepted this response.

Confidentiality Advisory Group advice: Conditionally supported

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 standard conditions of support.

Specific conditions of support

The following sets out the specific conditions of support.

1. Please provide updated information to CAG, which shows how many people respond to the PPI questionnaire, such as a summary of issues/concerns raised or whether people are generally supportive, within one month.

2. The presence of a lay member should be a condition of the quorum requirements for the Oversight Committee (which assesses data access requests). Please confirm to CAG within one month, with updated Terms of Reference.

3. Please revise the NDOO section on the poster to align with the changes made to the leaflet, to state they any choice previously made through the National Data Opt-out will be respected, and provide an updated poster to CAG for review, within one month.

4. Favourable opinion from a Research Ethics Committee. **Confirmed 10 July 2023**

5. 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 **22/23** DSPT reviews for **King's College Hospital NHS Trust, Guy's & St Thomas' NHS Trust & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 09 November 2023)

c.

23/CAG/0141	**Kings College Hospital Liver Intensive Therapy Unit Research Database**
Chief Investigator:	**Professor William Bernal**
Sponsor:	**King's College Hospital NHS Foundation Trust**
Application type:	**Research Database**

Present:

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Dr Rachel Knowles	CAG Member (Expert)
Mr Andrew Melville	CAG Member (Lay)
Mrs Sarah Palmer-Edwards	CAG Member (Expert)
Mr Umar Sabat	CAG Member (Expert)

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

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

Summary of application

This application from King's College Hospital NHS Foundation Trust set out the purpose of medical research which aims to create a research database from existing information relating to people treated at the Liver Intensive Therapy Unit (LITU). The LITU is a unique specialist Intensive Care Unit that has been in existence since 1973, and since opening has cared for a very large number of critically ill people with a wide variety of liver diseases. The database will enable new studies in important aspects of the care of critically ill people with liver disease, which will include understanding the natural history of the conditions treated at the LITU, the changes seen over time and the effects of specific treatments, detailed statistical modelling to identify thresholds for the use of particular treatments including liver transplantation, and 'bench-marking' the outcome for specific conditions, to allow comparison to be made over time and between treating units.

The database will collate existing datasets relating to patients treated at the Liver Intensive Therapy Unit (LITU) at the Institute for Liver Studies (ILS) at Kings College Hospital, London. Identifiable data relating to the adult patients treated at the LITU is currently held securely in 3 legacy systems accessed only by the Direct Care Team. The research database will include data only for adult patients treated on the LITU, covering the period 1973-2023 with a core dataset of demographics, diagnosis and outcome common to all datasets. The only current plans for future data collection are for periodic updating of survival and opt-out status to be undertaken independently by the Business Intelligence Unit at Kings College Hospital using the hospital numbers held separately from the research database as part of the linkage file that contains both hospital and

Study numbers. ‘s251’ support is required because the Trust Caldicott guardian has confirmed that the Business Intelligence Unit are not considered to be part of the direct care team.

All access to and use of the database for research projects will be approved by the Data Access Committee (DAC) which will report regularly to the Care Group Research Governance Committee. The DAC will have lay representation, and terms of reference have been submitted. All research will be for a medical purpose, and assessed by the DAC as being in the public interest. All outputs provided to researchers will not include any identifying information.

Confidential information requested

Cohort	Approximately 15,000 adult patients treated on the LITU, covering the period 1973-2023
Data sources	1. Medical records from King's College Hospital NHS Foundation Trust from the following sources; a. LITU Acute Liver Failure Registry. b. The MEDTRACK Dataset. c. Intellispace Critical Care and Anaesthesia (ICCA) data management system. d. Physiology and laboratory data from KCHNHSFT data warehouse 2.NHS England a.NHS Spine
Identifiers required to be retained in the database	1. Date of birth (for updating survival) 2. Date of death (modified for analysis) 3. Gender 4. Ethnicity 5. Sector level postcode 6. Hospital number (for updating survival) 7. Database number
Identifiers required for analysis purposes	1. N/A analysis will be on pseudonymous data only
Additional information	Identifiers will not be held in the same database as the clinical data, but separately in a distinct database held elsewhere within the Trust network with access limited to senior staff managing the database and the from the Trust Business Intelligence Unit who will undertake any required update of case survival and opt-out status. This linking database will include both hospital number and a unique database number.

	NHS Spine checks will be annual.

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

#	Action required	Response from the applicant
1.	Please revise the following with regards to the patient notification materials: a. Update the poster, ensuring that it is engaging, and in lay language. b. State that the LITU is a research active unit. c. Clarify on both the poster and website that some identifiers would be kept for linkage purposes. d. Clarify the cohort dates on both the poster and the website. e. Remove the link to the National Data Opt-Out within both notifications and ensure that statements about the opt-out options are consistent between the poster and website notification.	a. Please see revised poster (LITU Notification Poster v2.0 09/10/23) b. Done (para 1) c. Done (para 5) d. Done (para 4) e. Done (See poster v2.0 and Patient Facing Website Text Draft 1.2 16/10/23 with changes marked. Changes and links requested by REC also incorporated) CAG were content with this response
2.	Please confirm that identifiers will be deleted after patients have deceased.	Confirmed CAG were content with this response
3.	Include into section 1.2 of the TOR that all research will be assessed by the DAC as an appropriate medical purpose, and in the public interest.	Done; see TOR v1.1 9/10/23 (marked) CAG were content with this response
4.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place. This is currently **Pending**	Favourable opinion 17/10/23 CAG were content with this response

Confidentiality Advisory Group advice: Conditionally supported

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 standard conditions of support.

Specific conditions of support

The following sets out the specific conditions of support.

1. 's251' support is in place for 5 years from the date of this letter. A duration amendment will be required at that time if 's251' support is still required.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 17 October 2023**

3. 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 **22/23** DSPT reviews for **King's College Hospital NHS Foundation Trust & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 09 November 2023)

d. 23/CAG/0107 - Emergency Surgery Or noT for common Vascular conditions in the periods before and during COVID-19 (the ESORT-V study)

Name	Capacity
Mr Tony Kane	CAG member
Dr Harvey Marcovitch	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application from London School of Hygiene & Tropical Medicine set out the purpose of aiming to investigate how effective and cost-effective urgent surgery is compared to elective surgery for patients with common vascular conditions. The study will generate evidence about which patient subgroups benefit most from urgent surgery, those in whom elective surgery may be more cost-effective, and those for whom there is sufficient uncertainty around the relative risks and benefits of urgent intervention. The results will inform service design for vascular surgery, National Institute for Health and Care Excellence (NICE) clinical guidelines, Getting It Right First Time (GIRFT) and commissioning guides for acute services.

Patients require surgery on their blood vessels to help prevent the likes of stroke, limb removal and death. Some patients require urgent surgery, but others may benefit from receiving treatment or attending exercise classes first, before undergoing surgery. There is little evidence currently available on the benefits of having surgery sooner or later. Covid-19 has reduced the ability of the NHS to meet recommended waiting times for patients receiving surgery. Waiting lists for planned surgery are approaching 10 million patients and advice is urgently required on how to sort patients into those who will benefit from receiving surgery soon versus those who would benefit from surgery at a later date.

Eligible patients will be identified within the National Vascular Registry (NVR), which is commissioned by the Healthcare Quality Improvement Partnership (HQIP). Patients undergoing elective surgery are included in NVR via consent. For patients undergoing emergency surgery, support under Regulation 5 is in place via application CAG 5-07(f)/2013. The NVR will disclose confidential patient information, together with a study specific ID, to NHS England to facilitate linkage with HES and ONS. Wider clinical information from the NVR will be released to the applicant with the same study-specific ID attached. NHS England will undertake linkage to HES and ONS and release this information to the applicant with the study-specific ID attached. ‘s251’ support will be required for the flow back, as the applicant will receive full date of death. The applicant will link the two datasets together using the pseudo-ID, and date of death will be modified for analysis.

A recommendation for class 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 who undergo one of the vascular surgical procedures of interest on an urgent or elective basis from 01 January 2016 up to the most recent available data. The populations and procedures of interest are: • Patients with non-ruptured AAA undergoing AAA repair • Patients undergoing carotid endarterectomy (CE) after stroke/transient ischaemic attack (TIA) • Patients with peripheral arterial disease (PAD) undergoing lower limb revascularisation/amputation. Approximately 51,000 (however 's251' support only covers those patients who are not consented into NVR)
Data sources	1. National Vascular Registry (NVR) data, retained by the Royal College of Surgeons of England 2. NHS England – a. HES b. ONS
Identifiers required for linkage purposes	1.First name 2.Surname 3.Date of birth 4.Postcode 5.Gender 6.NHS number 7.Pseudonymous study ID
Identifiers required for analysis purposes	1.Full date of death received, but modified for analysis 2.Age 3.Ethnicity 4.LSOA 5.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. **Clearly explain within the patient notification material what confidential patient information is processed, for what purpose, and at what stage confidential patient information will no longer be processed, including options for dissent from this application specifically, and provide the updated documentation to CAG.**

A revised privacy notice has been drafted which includes further information about what information is processed, the purpose of this, at what stage the information will no longer be processed and options for dissent from this application specifically, including

options for opt-out, after engaging in further conversations with the NVR. CAG were content with the revised documentation.

2. **Please ensure the revised notification is reviewed by the patient and public involvement group and discuss the use of confidential patient information without consent.**

The revised notification was reviewed by 5 patient and public contributors who reviewed the materials carefully and provided their feedback. Contributors provided feedback on the clarity of the document, its' accessibility and whether any pertinent elements had been omitted. Contributors fed back that the document was accessible and informative. They had several suggestions for amendments. These included providing a glossary at the end of the document, including more hyperlinks to relevant websites and clarifying how outcomes of interest for the study were derived. The notice was revised and finalised on the basis of this feedback. The CAG were content with this response.

3. **Please undertake further patient and public involvement with additional individuals, specifically discussing the use of confidential patient information without consent.**

In early September 2023, applicants held two online meetings with individuals who had direct or family experience of surgery, or of using patient information records. A total of 14 patient and public representatives attended these discussions. Patient and public representatives were provided the opportunity to learn about the ESORT-V project and share their views on the use of confidential patient information without consent. Attendees were clear about the importance of this research and understood that accessing patient information without consent was necessary to address the crucial questions being asked as part of this study. They reassured applicants that plans for accessing and analysing this data were clear that using routinely collected patient information brought together from different NHS records was essential to resolve existing uncertainties. None of the attendees objected to the use of confidential patient information without consent as part of this study. CAG were content with this response.

4. **Please provide the NHS England 22/23 DSPT review for London School of Hygiene & Tropical Medicine, as per standard condition of support.**

This was provided to the CAG inbox on 08 November.

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. 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 22/23 DSPT reviews for **London School of Hygiene & Tropical Medicine**, **NHS England** and **Royal College of Surgeons of England** were confirmed as Standards Met on the NHS England DSPT Tracker (checked 08 November 2023)

e.

23/CAG/0131	Integrated Care Experience Survey (Phase One)
Contact:	Terunnum Shakeel
Data controller:	NHS England
Application type:	Non-research

Members present:

Name	Capacity
Professor William Bernal	CAG Alternate Vice Chair
Ms Clare Sanderson	CAG Alternate Vice Chair
Dr Sandra Duggan	CAG Lay Member
Dr Ben Gibbison	CAG Expert Member
Mr Andrew Melville	CAG Lay Member
C. Marc Taylor	CAG Expert Member
Professor James Teo	CAG Expert Member

Also in attendance:

Name	Position (or reason for attending)

Mr William Lyse	HRA Approval Administrator
Ms Emma Marshall	HRA Confidentiality Specialist
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Angelika Kristek	External Observer (Clinical Research Facilitator at Royal Berkshire NHS Foundation Trust, and a member of Dulwich REC)
Jane Oakley	Internal Observer (Head of Public Involvement at the HRA)

Summary of application

This non-research application submitted by Ipsos UK on behalf of NHS England, sets out the purpose of conducting The Integrated Care Experience Survey (ICES). The purpose of this survey is to allow ICBs to understand how well integrated care is working for people with multiple and complex needs and their informal carers. The survey data will be used to understand how well integrated care is being delivered and to help inform improvements in service delivery. This information will be used to inform the NHS Oversight Framework, Care Quality Commission assessment of ICSs, and evaluations of ICSs by both NHS England and the Department of Health and Social Care.

The survey sample will be compiled by each participating ICB (by their own data processor) from GP Practice data using a set specification. Eight ICBs are expected to participate in Phase One. A sample of up to 5,000 people per ICB will be invited to participate in the survey. The survey sample data including confidential patient information, will be transferred to Ipsos UK, which requires 's251' support. Ipsos UK will generate a unique survey identification code for each potential participant and conduct the deceased service users check. Confidential patient information will also be disclosed from Ipsos UK to Formara and Text local, for the purposes of Formara sending postal questionnaires and survey invitation letters, and Text Local sending SMS. Ahead of each mail out, those who have already responded will be removed from the sample file and deceased checks will be repeated.

The survey will follow a similar mixed method approach as other surveys also carried out by Ipsos UK. The contacts will be as follows;

Contact	Type	Content of contact	Days from first mailing
1	Postal	Invitation letter inviting the patient to take part online	1

1.1	SMS	SMS reminder (if phone number available), 3 days after mailing 1	4
2	Postal	Reminder letter	14
2.1	SMS	SMS reminder (if phone number available), 3 days after mailing 2	17
3	Postal	Reminder letter, Paper questionnaire, Freepost return envelope	28
3.1	SMS	SMS reminder (if phone number available), 3 days after mailing 4	31

Confidential information requested

Cohort	Approximately 40,000 patients with clinically complex needs identified though GP records based on their electronic Frailty Index score (eFI)
Data sources	1. GP medical records from 8 participating ICBs: a. Bristol, North Somerset and South Gloucestershire ICB b. Derby and Derbyshire ICB c. North East and North Cumbria ICB d. Devon ICB e. Lancashire and South Cumbria ICB f. Norfolk and Waveney ICB g. South West London ICB h. Sussex ICB
Identifiers required for purposes of identifying the cohort and sending invitation to consent	**Identifiers for sample checking:** 1. Date of birth, 2. Gender, 3. Ethnic group, 4. NHS number, 5. Postcode, 6. GP practice code, 7. ICS code, 8. eFI score, 9. GP practice registration date **Identifiers required for conducting deceased checks:** 1. Name (full), 2. Postcode, 3. Date of birth, 4. NHS number, 5. Gender

	Identifiers required for sending invitation letters/surveys and SMS reminders: 1. Title, 2. Name (full), 3. Full Address, 4. Postcode, 5. Mobile numbers (where recorded), 6. ICS code
Identifiers required for analysis purposes (disclosed to IPSOS UK prior to implied consent in place)	**Analysis will be undertaken with implied consent, however the following data items are disclosed to IPSOS UK prior to consent is received;** 1. Postcode, 2. Date of birth, 3. Ethnic Group, 4. GP Practice code, 5. ICS code, 6. eFI score, 7. GP practice registration date

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

#	Further Information required	Response from the applicant
1	Please provide to CAG further information which shows how the questionnaire would yield data that would result in patient benefit, providing specific examples, in order to evidence the public interest in the breach of confidentiality.	The applicant provided a document 'Question 1 v1.0' which contains a detailed response including information about how the questionnaire would yield data resulting in patient benefit. This explains that the ICES is a new nationally coordinated data collection which will allow ICSs to understand how well integrated care is working for people with multiple and complex needs and their informal carers. The specific purpose of the survey is to look beyond interactions with specific services and to consider the way integrated neighbourhood teams – across primary care, community services, social care, the voluntary sector – are working together to join up and better coordinate interactions. As such, this is not about singling out any one particular part of the

#	Further Information required	Response from the applicant
		service, but how multi-disciplinary teams are working together to support people through continuity, more streamlined personalised care and proactive support. In order to support the move to partnership working this new nationally coordinated data collection will enable ICSs to look at experience of care across the whole system, to reassess what good joined up care looks like, particularly for people with multiple or complex needs stretching across a number of traditional service boundaries. The CAG considered the information provided, and were content to accept the justifications of the applicant.
2	Please undertake further patient and public involvement and engagement, specifically focussing on the use of confidential patient information without consent.	Additional patient and public involvement and engagement has been carried out specifically focusing on the use of confidential patient information without consent. A document 'Question 2 v 1.0 includes patient feedback. The CAG were content with this response.
3	Please provide justification regarding the amount of contacts, and the speed of the SMS contact, potentially discussing with patient and public involvement representatives regarding if sending 3 invitation letters and 3 SMS messages is too intrusive.	The applicant provided a document 'Question 3 v1.0' which contains a detailed response including justification regarding the methodology. The response includes details of discussion with patient and public involvement representatives. The justifications provided included industry evidence, other surveys (for example CQC mixed methodology surveys), and patient feedback. The timings between reminders have to be carefully balanced between what is known to provide maximum impact (i.e. a higher response rate) and the day-to-day practicalities of administering large scale surveys. The core approach is that all reminders should build on or reinforce previous contacts. For example, SMS reminders are often timed to arrive at the same time as the paper

#	Further Information required	Response from the applicant
		reminders, thus reinforcing the contact and this is the approach we are proposing for ICES. SMS reminders will be sent 3 days after each of the paper mailings. Paper reminders need to be spaced so that they "remind" patients of previous contacts rather than the gap being so large they act as a "new" contact. While the proposed contact approach for the ICES is based on evidence from across the industry and other in-house patient surveys, Ipsos operate on a "respondent first" approach to all surveys. This means that the core ethos is to ensure that surveys "make sense" to the people that are contacted and put their needs first. In practice, this means that on almost all large scale projects, applicants go through a thorough cognitive testing phase to test both the materials and the questionnaires. As part of this phase, patients are asked about the wording of the contact materials (i.e. the letters and SMS), the mode and the frequency. Across all surveys there has been acceptance and expectation from participants that they will be contacted by both post and SMS. Respondents regularly point out that they are contacted via these modes by other organisations both from within the NHS (such as GPs and dentists), and outside the NHS (such as banks), so this contact is understood and familiar. The frequency of contact has not raised concerns with patients during the cognitive interviews across any of the large surveys. When gently probed on this area, patients commented that they would merely "put the invites in the bin" if they didn't want to receive them or contact the helpline if they wanted to opt-out. Across all large surveys, applicants monitor "communications" during fieldwork so that they can feed any learning points into future waves or other

#	Further Information required	Response from the applicant
		surveys. To date, across the surveys detailed in the accompanying document, there have been minimal (or no) complaints about the number of contacts or higher opt-out rates. Thinking specifically about the ICES, applicants discussed the initial invitation letter, reminder letters and SMS reminder with thirty people, 18 people living with complex health and care needs and 12 carers of people living with complex health and care needs. Participants were positive about the reminder letters, noted that they liked the SMS reminders and would be happy to receive them. Applicants acted on participant feedback by adding a note to the letter to make participants aware that they may also be contacted by SMS and will ensure that SMS reminders are sent in the morning or early afternoon, rather than the evening in line with participant preference. The CAG were content with this response.
4	Please amend the initial contact letter; a. explaining the data items used and the flow more clearly b. clearly explain the role of CAG and the legal basis which allowed the patient to be identified, and why and how they are receiving a letter.	4a) The initial contact letter (and reminder letters) have been updated to explain the data items used and the flow more clearly. Given the complex nature of the sampling (use of the electronic frailty index score which is calculated using 36 deficits), applicants will add additional information to the NHS England privacy notice ahead of the survey going live. Applicants will test this information with patients and are happy to share the final privacy notice with CAG. This change has been made (and tracked) in the following documents (all attached) within the folder 'Questions 4 and 5': · ICES People Invitation Letter v0.3 · ICES People 1st Reminder Letter v0.2 · ICES People 2nd Reminder Letter v0.2 4b) This change has been made (and tracked) in the following documents (all attached) within the folder 'Questions 4 and 5': · ICES People Invitation Letter v0.3

#	Further Information required	Response from the applicant
		· ICES People 1st Reminder Letter v0.2 · ICES People 2nd Reminder Letter v0.2 · ICES Carer Information Sheet v0.2 CAG were content with this response
5	Please consider whether the phrase; '*and then decide whether to keep them for longer*' should be removed from the notification, and data deleted after 20 years (or less).	The survey invitation letters originally included the wording *"and then decide whether to keep them for longer"* to ensure that data could be kept for longer than 20 years if there is a clear need to do so. This wording has been used on recent iterations of the Cancer Patient Experience Survey without evidence of negative impact on participation. However, after careful consideration, in the interests of trying to encourage participation in relation to this specific survey cohort, applicants have decided to remove the wording *"and then decide whether to keep them for longer".* This change has been made (and tracked) in the following documents (all attached) within the folder 'Questions 4 and 5': · ICES People Invitation Letter v0.3 · ICES People 1st Reminder Letter v0.2 · ICES People 2nd Reminder Letter v0.2 · ICES Carer Information Sheet v0.2 The CAG were content with this response.

Confidentiality Advisory Group advice: Fully supported

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care subject to compliance with the standard conditions of support.

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 organisations 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 an organisation. These will not be individually checked by the CAT team due to the number of organisations involved.

f.

23/CAG/0156	**Development of Pathways for the Diagnosis and Management of Latent Tuberculosis Infection in Wales**
Chief Investigator:	Dr Emma Thomas-Jones
Sponsor:	Public Health Wales
Application type:	Research

Present:

Name	Capacity
Dr Murat Soncul	Alternate Vice Chair
Dr Malcolm Booth	CAG Expert Member
Mr David Evans	CAG Expert Member

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

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

Summary of application

This application from Cardiff University (with the data controller confirmed to be Public Health Wales) set out the purpose of medical research that aims to develop new screening guidelines for Tuberculosis (TB) in Wales, for patients due to be

immunosuppressed, by retrospectively reviewing existing data to determine what method would be most cost-effective and have the fewest problems related to antibiotic treatment (WP1). There are further aims relating to WP2, but this is out of scope for CAG support.

TB is an infectious disease. When a person becomes infected, they may either develop an active and infectious form of the disease, or their immune system can control it, such that it lies dormant until potentially 'activated' later. This is called latent TB infection (LTBI). Identifying and treating people with LTBI is crucial to preventing the spread of TB, and this is done with a blood test that measures how immune cells release specific chemical signal.

In WP1, Participants will be identified through Public Health Wales (PHW) databases containing retrospective LTBI screening data from the last 7 years. WP1 requires 's251' support for the disclosure of confidential patient information (date of birth and NHS number), alongside IGRA screening test outcome and adverse treatment outcomes, from the LTBI Screening Database at PHW, and from the LTBI Screening Database at Oxford Immunotec Ltd (for which PHW is controller), to the applicant via a PHW laptop. Confidential patient information is necessary, as results of screening tests and adverse effects of antibiotic treatment may need to be accessed for clarification. This will only be done by the applicant, if data is missing, by undertaking checks using NHS number and date of birth, by accessing the Welsh Clinical Portal controlled by Digital Health and Care Wales (DHCW). The data will then be anonymised and disclosed to Cardiff University - Centre for Trials Research.

Confidential information requested

Cohort	WP1: approximately 20,000 patients of any age in Wales who have been screened for latent TB using an IGRA from 2015 – 2022
Data sources	1. LTBI Screening Database - Public Health Wales 2. LTBI Screening Database - Oxford Immunotec Ltd (Public Health Wales are controller for this data) 3. Welsh Clinical Portal – Digital Health and Care Wales (DHCW)
Identifiers required for linkage purposes	1. Date of birth 2. NHS number
Identifiers required for analysis purposes	1. District level postcode Applicant states anonymous for analysis.

Confidentiality Advisory Group advice

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

#	Action required	Response from the applicant
1.	Clarify the retention period of confidential patient information on the researcher's laptop before it is anonymised.	The dataset containing PII will be held on the PHW laptop only for the duration of the PhD (expected completion April 2026), after which it will be deleted from use by the research team. PII (i.e. NHS number) for each participant will be deleted as soon as linkage between data sources has been completed and all the relevant data collected per person. All data transferred from PHW to Cardiff University for write up will be fully anonymised. CAG were content with this response.
2.	Confirm whether full name is required for linkage purposes.	Full name is **not** required for linkage of data. CAG were content with this response.

Confidentiality Advisory Group advice: Fully supported

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 standard conditions of support.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 5 September 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. **Confirmed:**

   The NHS England **22/23** DSPT review for **Oxford Immunotec Ltd** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 10 November 2023)

Public Health Wales (PHW) & Digital Health and Care Wales (DHCW) security assurances are confirmed by the Welsh IG team, in the form of valid CPiP reports or Welsh IG toolkits.

g. 23/CAG/0075 - A Multi-Center Registry of Cardiovascular Magnetic Resonance Data for Research, Education, and Quality Control Purposes

Name	Capacity
Dr Murat Soncul	Alternate Vice Chair
Mrs Sarah Palmer-Edwards	CAG Expert Member
Professor Sara Randall	CAG Lay Member
Ms Rose Payne	CAG Lay Member
Ms Katy Cassidy	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from King's College London and Guy's and St Thomas NHS Foundation Trust set out the purpose of creating a research database to evaluate the impact and benefit of cardiac magnetic resonance imaging for the diagnosis and prognosis of cardiac pathology.

Over 100,000 patients each year in the UK receive cardiac MRI imaging for the purpose of diagnosis or the evaluation of heart disease. Most exams are reviewed for immediate clinical needs only and are not used to evaluate the cost/benefit or for quality assessment. The applicants seek to use data already collected as part of clinical care to evaluate which types of imaging protocols are run, and the relationship between imaging markers and outcomes. The applicants also seek to develop and validate machine learning methods of deriving imaging biomarkers.

An anonymised database of patients who have undergone MRI imaging for the diagnosis or evaluation of heart disease will be created. Patients meeting the inclusion criteria will be identified by either the clinical care team or by a member of the research team at the participating sites. A dataset containing items of confidential patient information will be disclosed to NHS England for linkage to HES and ONS datasets. Once the linked data is returned to the participating Trust, an anonymised dataset will be disclosed to King's College London to create the SCMR Registry.

A recommendation for class 1, 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application, which can be got from the CAT assessment form, class support requested section.

Confidential patient information requested

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

Cohort	All patients who underwent MRI imaging for the diagnosis or evaluation of heart disease at Guy's and St Thomas' NHS Foundation Trust or Leeds Teaching Hospitals NHS Trust between 1 Jan 2010 and present (1 Jan 2024 at the latest).
Data sources	1. Electronic and paper patient records at Guy's and St Thomas' NHS Foundation Trust and Leeds Teaching Hospitals NHS Trust 2. HES and ONS data, held by NHS England
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Postcode 4. Date of birth 5. Gender
Identifiers required for analysis purposes	1. Gender 2. Ethnicity
Identifiers retained in the research database	1. Year of birth 2. Gender 3. Ethnicity

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

Clarify how this research relates to the registry held in the USA.

The applicant clarified that the UK SCMR research database will collaborate with the central SCMR Registry to make de-identified CMR data available to the global research community The UK registry lead applicant (PI) will be the lead point of contact for data access requests from the central SCMR registry hosted in the USA.

The CAG were content with this response.

Clarify how access to the anonymised research dataset will be managed.

It was confirmed that the central SCMR Registry Committee will review all data access requests and contact the UK Registry Principal Investigator with approved requests. The UK PI will present the request to the local imaging data access committee for approval before access is granted.

The CAG were content with this response.

Clarify whether the Committee reviewing applications for research using this research data base is based in the USA or the UK. The CAG noted that any decision involving UK data needs to include UK representation. If the Committee was not UK-based, then a UK representative needed to be included.

The applicant confirmed the committee is based in the UK.

Members raised no further questions.

Provide details on plans for expansion and future partnerships.

The applicant confirmed that discussions were ongoing with other Trusts to expand the contributing sites in the UK.

The committee were content with this response, though reminded the applicants that an amendment will be necessary to expand the contributing sites.

Justify why gender and patients' postcodes are also required to facilitate the data linkage.

The applicant clarified that gender and postcodes are not required for linkage.

CAG requested that these are removed from the list of items for linkage, to which the applicant agreed.

Patient notification materials need to be created. The materials must include the following:

a) **A layered approach is to be adopted.**

b) **The materials need to be proof-read to ensure lay language is used.**

c) **The purpose of the research and lay language explain the research and justify the use of data.**

d) **An explanation on how patients can request removal of their data using a local opt-out or the National Data Opt-Out needs to be provided. The CAG usually expects that telephone, email and postal contact details are provided, should patients have queries or wish to dissent to the inclusion of their data.**

e) **All notification material to be reviewed by a patient and public involvement group.**

The applicant provided a response to confirm that the notification will be created and cover these points. CAG were not content with this response and requested sight of the proposed notification materials.

A draft document informing patients was subsequently provided. CAG were broadly content with this document, though recommended the applicant review and update the patient notification materials to:

- Ensure that project specific opt out takes prominence over the National Data Opt Out
- Rephrase the NHS digital opt-out service as National Data Opt Out
- Ensure consistency of use of “you” or “I” throughout the document

Further patient and public involvement, particularly around the specific issue of use of confidential patient information without consent is to be undertaken and feedback provided to the CAG for review.

The applicant confirmed that the next PPI event will be held in October 2023, to which the CAG were content with.

Provide an estimation of the cohort size and how it might increase as the research progresses.

Initially the cohort is expected to be about 5,000, but could expand to 20,000.

This was accepted by the CAG.

Confidentiality Advisory Group advice conclusion
The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 22 June 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. **Confirmed:**

   The NHS England **22/23** DSPT review for **Guy's and St Thomas' NHS Foundation Trust, King's College London and Leeds Teaching Hospitals NHS Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker

h. 23/CAG/0139 - Retrospective cohort study of professional footballers in England

Name	Capacity
Dr Pauline Lyseight-jones	CAG Lay Member
Mr Dan Roulstone	CAG Lay Member
Mr Umar Sabat	CAG Expert Member
Ms Clare Sanderson	Alternate Vice Chair
Mr Marc Taylor	CAG Expert Member
Emma Marshall	HRA Confidentiality Specialist

Context

Purpose of application

This application from the Institute of Occupational Medicine (IOM) sets out the purpose of creating a research database of former professional footballers aged over 40 who have died to understand whether mortality rates from neurological disorders are higher in former professional footballers than the general population of England and Wales. It also aims to look at aspects of participants playing career such as the estimated lifetime numbers of headers, playing position and level played at, which may be important in relation to risk of neurological disorders.

The study cohort (as detailed below) will be identified and collected by the IOM from the publicly available database Barry Hugman's Footballers (barryhugmansfootballers.com). The study cohort identifiers will be sent from IOM to NHS England for linkage and to request mortality data. Support is requested to allow the disclosure of confidential patient information for the study cohort from NHS England's mortality data to the IOM and for IOM to create a pseudonymised research database.

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	Professional footballers aged over 40
Data sources	1. Barry Hugman's Footballers database
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Date of death 4. Geographic location based on the club played for e.g. Nottingham Forest = Nottingham
Identifiers required for analysis purposes.	1. Month and year of birth 2. Month and year of death 3. Region of England at time of death 4. Ethnicity
Additional information	Estimated number of participants 15-20,000

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.

If the applicant wishes to operate a research database, an amendment would need to be submitted to CAG including detail on the following:

a. A breakdown of the number and types of membership of the data access committee

b. The terms of reference for the data access committee including the criteria used to determine applications to access the data (applications should always have a medical purpose)

c. Further detail on how the data will be protected. This should include consideration around the risk of re-identification of the pseudonymised data given that some data is already in the public domain

The applicant confirmed that they do not intend to produce a research database and that the data set for this study is for a one-off analysis.

The CAG accepted this.

Revise the patient notification leaflet as follows:

a. Amend the current description surrounding CAG having 'approved' the study. The following wording should be used: 'The application was reviewed by the Confidentiality Advisory Group (CAG). CAG is an independent group of lay people and professionals which provides expert advice on the use of confidential patient information without consent. CAG recommended that our application should be supported, and the Decision Maker within the Health Research Authority approved this'

b. Clearly outline the purpose of the study and why the study is being undertaken.

c. Clarify how those affected within the study would be notified of the results.

d. Clarify that those who opt-out will only be opting out of their data being linked for the purposes of this study.

The applicant submitted a revised patient notification leaflet addressing the points raised.

The CAG were content with this.

Provide plans for further patient and public involvement work to include representation from those over 40 who are alive and may be affected by the study. This should include seeking views on the breach of patient confidentiality when linking data.

The applicant confirmed that they would make a presentation of the findings of the results of the study to PFA and its members, before the study is published and would inform Dr White (head of brain health at the PFA) of this.

The CAG were content with this.

Clarify how the research team intend to disseminate the results of the study.

Aside from the presentation and leaflet for onwards distribution by the PFA, we also intend publishing our findings in a peer-reviewed scientific journal. Depending on our findings, we may also engage with the Science Media Centre in the dissemination to non-scientific sources.

The CAG accepted this.

Confidentiality Advisory Group advice conclusion
The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Section 251 support is provided for the duration required to link the data

2. Favourable opinion from a Research Ethics Committee. **Confirmed 18 September 2023**

3. 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 **22/23** DSPT review for **Institute of Occupational Medicine** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 26 September 2023)

i.

23/CAG/0135	**VIVALDI Social Care**
Contact:	Professor Laura Shallcross
Data controller:	University College London

Application type:	Non-research

Present:

Name	Capacity
Professor William Bernal	CAG Alternate Vice Chair
Ms Clare Sanderson	CAG Alternate Vice Chair
Dr Sandra Duggan	CAG Lay Member
Dr Ben Gibbison	CAG Expert Member
Mr Andrew Melville	CAG Lay Member
C. Marc Taylor	CAG Expert Member
Professor James Teo	CAG Expert Member

Also in attendance:

Name	Position (or reason for attending)
Mr William Lyse	HRA Approval Administrator
Ms Emma Marshall	HRA Confidentiality Specialist
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Angelika Kristek	External Observer (Clinical Research Facilitator at Royal Berkshire NHS Foundation Trust, and a member of Dulwich REC)
Jane Oakley	Internal Observer (Head of Public Involvement at the HRA)
Zoë Fry OBE	Engagement lead for VIVALDI Social Care, & the *Executive Director for* The Outstanding Society CIC
Professor Laura Shallcross	Chief investigator
Dr Oliver Stirrup	Study statistician and senior post-doctoral research associate

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

Summary of application

This application from University College London (with the Outstanding Society and Care England confirmed to be joint controllers), set out the non research purpose which aims to create a database including data on infections, hospital attendances, vaccinations, antibiotic prescriptions, and deaths in older adults who live in care homes. Applicants will create the database by collecting and linking data on residents in these homes. The aim is to collect data from at least 500 homes and up to 30,000 residents in England. This is a pilot project – if it is a success, the goal is to establish a long-term programme of research and surveillance for infection in care homes, informed by learning from this application. This non-research application will aid policymakers to prevent and reduce outbreaks, and to protect people who live and work in care homes from infections.

Every year care home residents experience infections and outbreaks, which reduce their physical and mental health and well-being and cause avoidable hospital admissions and deaths. Many of these infections could be avoided with better evidence on 'what works in care homes' and systems to keep track of and therefore stop infection.

The database will require confidential patient information to be collected from care homes and disclosed to Arden & GEM CSU, in order for NHS England to link to NHS and public health datasets, including records of vaccination, hospitalisation, and death. The database will then be effectively anonymised before it is shared with UKHSA. The effectively anonymous data collected will be used to measure and prevent infections in residents and stop them spreading. There is an associated research database study, which has been submitted to CAG separately – 23/CAG/0134.

Confidential information requested

Cohort	The cohort will include approximately 15,000-30,000 residents from 500-1500 care homes for adults older than 65 years in England. The data will be collected prospectively between 01 October 2023 and 31 March 2025
Data sources	1. Participating care homes records 2. NHS England – Linked routine datasets: -COVID-19 / Influenza tests -NIMS vaccination data -APC / ECDS hospital attendances data -ONS mortality data -SGSS microbiology and virology results -Antimicrobial prescriptions

	-HPZone, care home level data on outbreaks
Identifiers required for linkage purposes	1. NHS number 2. Care home post code based on care home CQC-ID (only the first 3 characters) 3. National Commissioning Data Repository (NCDR) pseudo-identifier
Identifiers required for analysis purposes	1. Applicants are linking to mortality data but are only receiving date of death in MM/YY format. 2. Gender 3. Ethnicity 4. Age 5. Care home post code based on care home CQC-ID (only the first 3 characters). Therefore data will be pseudonymised (effectively anonymised) for analysis
Additional information	The pseudonymisation key will be held by NHS England. Data will be linked daily.

Confidentiality 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

#	Action Required	Response from the applicant
1.	Please revise the notification materials: a) Amend the current description surrounding CAG having 'approved' the study, as the role of CAG is advisory, and research is approved by the Secretary of State for Health and Social Care on advice from CAG. b) Provide further detail with regards to the non-research database purpose. c) Clarify a start date for data collection on the notification materials. d) Please provide reference to feeding back the results to residents and relatives, as well as the care homes.	Applicants have amended the poster, residents' leaflet, relatives' leaflet, and detailed information sheet in line with these suggestions. CAG were content with these responses.

2.	Confirm whether the National Data Opt Out can be applied at the point of data extraction from care homes.	Applicants have discussed this with the digital software suppliers -(Nourish and Person Centred Software). They have confirmed that they will be able to apply the National Data Opt Out in addition to the study-specific opt-out (described in the CAG application and protocol) before residents' NHS numbers are sent to NHS England. The Data Flow Diagram has been updated accordingly (see Data Flow Diagram V2). CAG were content with this response.
3.	Please provide updated responses to the physical data security questions in the CAG application form. a. Describe the physical security arrangements for the location where patient identifiable data is to be: i) Processed; and ii) Stored (if these are different) b.System Information: Identify the type of system and application to be used for information processing including product version numbers where known (e.g. desktop PC, Laptop PC, MS Access, etc) Confirm if the computer system will be entirely standalone or connected to a LAN or WAN network, or be otherwise accessible remotely by another means such as dial-up modem. If so please confirm which networks these are and what they are used for, and provide a copy of the Network Security Policy. Provide details of access and/or firewall controls implemented on: i) This system; and	<u>Response from NHSE / AGEM:</u> a.The pseudonymisation and cleaning of this data will be through Arden & GEM Data Services for Commissioners Regional Office (DSCRO). The DSCRO uses a Regional Processing Centre (RPC) to provide a safe and accredited service to de-identify data, prior to it being passed to analytical teams for interrogation. This process is used for all identifiable data used by NHS England for purposes such as this. In the DSCRO the data are stored on secure file servers, separate to de-identified data, with enhanced access and security controls. b.Secure file servers are housed in server rooms/data centres with appropriate physical access and monitoring procedures. The network has multiple layers of protection, including firewalls, which are actively monitored to ensure that data are secure. c.The System Level Security Policy (SLSP) for the DSCRO is lodged with NHS England, being validated and signed off through their processes.

	ii) Any LAN or WAN to which it is connected Please also identify who is responsible for the management of these arrangements. c.System-level Security: Is there a system level security policy for this system? If yes, please supply a reference copy and confirm its status. Has the system ever been the subject of a security risk review? If so, please provide details and confirm whether all the necessary recommendations have been implemented. Please provide details of the arrangements you have implemented to routinely monitor and audit the security of this system for potential misuse or abuse.	The CAG were content with this response.

Confidentiality Advisory Group advice: Conditionally supported

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. At annual review, provide an updated definition of 'surveillance' which describes the non-research purposes more clearly, and provide an update on all the non-research uses of the data undertaken so far, in terms of public benefit.

2. Increase the number of care home residents in further patient and public involvement undertaken over the next year and report these discussions to CAG at annual review.

3. Undertake further patient and public involvement and engagement with care

home residents, around the feasibility of implementing a non-research opt out which is separate from a research opt out, and report these discussions to CAG at annual review.

4. 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 **22/23** DSPT reviews for **NHS England & Arden and GEM Commissioning Support Unit** (AGEM CSU/DSCRO) were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 November 2023)

   Due to the number of care providers and/or software vendor organisations involved, it is the responsibility of University College London, as controller, to ensure that processing 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 about an organisation.

j.

23/CAG/0133	Co-producing an Ambulance Trust national fatigue risk management system for improved Staff And Patient Safety (CATNAPS)
Contact:	Professor Kristy Sanderson
Data controller:	University of East Anglia
Application type:	Research

Present:

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Dr Rachel Knowles	CAG Expert Member
Mr Andrew Melville	CAG Lay Member

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

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

Summary of application

This application from University of East Anglia set out the purpose of medical research that aims to co-produce and test a comprehensive fatigue risk management system for the NHS Ambulance sector, that meets the needs of staff and operations and is most likely to improve patient and staff safety. The primary output from the collected data is a collection of recommended actions to reduce fatigue and promote sleep health in NHS ambulance staff, collectively referred to as a fatigue risk management system (FRMS). To help meet this aim, the applicants have a number of different work packages, including undertaking observations whilst out on call with the ambulance crews and in the emergency operations centres (EOC - call centres).

The applicants have discussed with the data controllers – ie. the Ambulance Trusts, who have agreed that an application to CAG is required for individuals who are not considered part of the direct care team, to undertake observations in the described scenarios. Support under Regulation 5 is requested for this aspect of the study as the applicants may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded, and patients are not the focus of the observations.

Observers will accompany ambulance crews and EOC staff on a run of 4 consecutive shifts, typically 2 day and 2 overnight (or late) shifts, and including one weekend shift where possible. The study will aim to observe the same members of staff over the consecutive observation period, however this may not always be possible due to staffing or sickness etc.

Confidential information requested

Cohort	Patients whose confidential patient information was discussed during clinical observations at participating Ambulance Trusts It is difficult to estimate a number of patients, as this will be an unknown quantity until the observations have taken place. Approximate estimate of 6 patients per shift.
Data sources	1. Clinical observations in participating Ambulance Trust ambulances and operations centres, recorded via written field notes, at the following Trusts;

	a. South East Coast Ambulance Service NHS Foundation Trust b. East of England Ambulance Service NHS Trust c. South Western Ambulance Service NHS Foundation Trust Scottish Ambulance Service – (outside of CAG remit and will be covered by PBPP)
Identifiers required for linkage purposes	No items of confidential patient information will be recorded for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be recorded for analysis purposes

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

#	***Action Required***	**Response from the applicant**
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	The applicant provided this as per standard condition of support.
2.	Security assurances for 2022/23 are outstanding for the following organisations: • South East Coast Ambulance Service NHS Foundation Trust • South Western Ambulance Service NHS Foundation Trust As per validation queries, please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review	The final DSPT review was completed on 22 November 2023 as per standard condition of CAG support.

	the 22/23 DSPT submissions due to a CAG application.	
3.	Provide confirm that if ambulance staff are aware that a patient has registered the National Data Opt-Out, it will be respected.	Applicants confirmed that if ambulance staff are aware that a patient has registered the National Data Opt-out, the patient's decision will be respected. CAG were content with this response.
4.	Please clarify that the researcher will not observe any patient interaction where a patient or carer objects or does not consent.	CATNAPS researchers will not observe any patient interaction where a patient or carer has not consented or otherwise objects, and CAG were content with this response.

Confidentiality Advisory Group advice: Fully supported

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 standard conditions of support.

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT reviews for **South East Coast Ambulance Service NHS Foundation Trust , East of England Ambulance Service NHS Trust, & South Western Ambulance Service NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 22 November 2023)

k.

23/CAG/0164	**Under 16 Cancer Patient Survey 2023 to 2026**
Contact:	Peter Williamson
Data controller:	NHS England
Application type:	Non-research

Present:

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Dr Murat Soncul	Alternate Vice Chair
Dr Joanne Bailey	CAG Expert Member
Dr Malcolm Booth	CAG Expert Member
Dr Sandra Duggan	CAG Lay Member
Dr Ben Gibbison	CAG Expert Member
Dr Rachel Knowles	CAG Expert Member
Dr Pauline Lyseight-Jones	CAG Lay Member
Dr Stephen Mullin	CAG Expert Member
Professor James Teo	CAG Expert Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Dayheem Sedighi	HRA Approvals Administrator
Ms Flora White	HRA Member Support Administrator (Observer)
Ms Rachael Maddocks	HRA Member Management and Development Specialist (Observer)

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

Summary of application

This application from NHS England set out the purpose of conducting a survey into the experiences of patients under 16 years of age receiving treatment for cancer.

The National Cancer Patient Experience Survey (CPES), commissioned and managed by NHS England, is one of the ways that patient experience data for cancer patients in England is captured. The results of these surveys are used to help commissioners, providers and national policy makers to identify priority areas of improvement for services. The application supports the implementation of the NHS Long Term Plan, which recognises the importance of good patient experience alongside other outcomes. The plan specifically references obtaining patient experience feedback from children.

Picker will provide NHS Trusts (PTCs) with detailed sampling instructions to compile a sample of patients, a patient declaration list and a template in which to organise their data. Each participating NHS Trust will extract confidential patient information for the survey sample, taken from the Patient Administration System (PAS) and transfer a list of eligible patients to Picker. Picker will check the sample and create a single master file containing the mailing information (patient name and address), trust code, site code, trust name, site name, survey type, and unique reference number for each patient. This file will be securely transferred to Greens Ltd who will then mail out questionnaires to the home address of patients, addressed 'to the parent/carer of [patient name]'. An anonymous code will be used to track who responds so that two reminders can be sent to non-responders, with 2-3 weeks between mailings and any opt-outs removed. PECS Data Services Limited (PECS) will record the responses received, but this will be under patient consent.

Confidential information requested

Cohort	All children aged under 16 at the time of their care and discharge, with a confirmed primary diagnosis of cancer or a non-malignant brain, other central nervous system or intracranial tumour, who are aware of their diagnosis and have received NHS care and/or treatment for their cancer or tumour in England within a recent twelve-month period (e.g. Jan 1st – Dec 31st 2023 for the 2023 survey).
Data sources	1. NHS Principal Treatment Centres (PTCs)

Identifiers required for linkage purposes	1. Name 2. Address 3. NHS number 4. Sex 5. Ethnic group 6. Date of birth 7. Discharge date 8. Patient classification 9. ICD10 code or ICD11 code 10. ICD-O-3 site code 11. ICD-O-3 morphology code 12. Specialty code 13. Site code 14. Trust code
Identifiers required for analysis purposes	1. Postcode
Additional information	Confidential patient information for analysis will be held with consent as the legal basis.

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

Number	Action required	Response from the applicant
1.	Security assurances for 2022/23 are outstanding for the following organisations. • *Picker Europe Ltd* Please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	This was provided to the CAG inbox on 27th November, as per standard condition of support.

Recommendations:	
1	The CAG suggested that it would be good practice if the invitation letter included a mechanism that gave participants the opportunity to express whether they wanted to receive the letters inviting them into similar surveys

	in the future. No response is required to this.
2	The CAG also recommended that it would be good practice to include more information in the patient notification to explain how the data flows to Picker and how it is used, and the legal basis for not being consented. No response is required to this.

Confidentiality Advisory Group advice: Fully supported

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care subject to compliance with the standard conditions of support.

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 **22/23** DSPT reviews for **Picker Europe Ltd & Greens Ltd** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 27 November 2023)

2. New Amendments

CAG 7-06(a)/2013 – Investigating the accuracy of current estimates of self-harm

Name	Capacity
Dr Murat Soncul	CAG alternate Vice Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Bristol has 's251' support to carry out data linkage of ALSPAC and Hospital Episode Statistics (HES) data in order to enhance understanding in relation to the accuracy of current estimates of self-reported self-harm in the community and the long term risk of hospital admission for self-harm. It is intended that the findings would have potential value for health policy by raising awareness about the importance of self-harm and would lead to greater prioritisation of preventative measures.

This amendment sought support to extend the study to include data from primary care as well as secondary care. This will enable applicants to identify what proportion of the ALSPAC cohort has sought help from their GP for self-harm and identify predictors of help-seeking (using information from both ALSPAC and GP data). This primary care data will be collected from GP practices, using the same model as other data which is already provided to main ALSPAC from GP practices. Applicants also aim to develop a prediction model to help GP's to better identify young people who have self-harmed using Primary Care data. A major limitation of existing research in this area is that it is restricted to those individuals who have disclosed their self-harm to services. By combining together data from Hospital Episode Statistics and GP practices, alongside self-reported self-harm in ALSPAC, applicants can more accurately identify who has self-harmed, and thus improve the validity of the prediction model. This will overcome limitations of previous research. Without this amendment, the analysis will be limited to secondary care services, enabling applicants to identify only the most severe cases of self-harm.

The primary care data that applicants will collect includes:

- Family history of mental illness
- History of mental illness, including specific conditions that are common in childhood/adolescence (depression, anxiety, eating disorders, ADHD and conduct disorder, autism spectrum disorder, suicidal thoughts)
- History of / current substance abuse, including smoking, alcohol and other drugs
- Involvement of social services
- GP consultation rates
- Body mass index

- Chronic conditions such as asthma, eczema, and diabetes
- Somatic symptoms (headache, stomach ache, pain etc)

The additional data collected from GP practices is not confidential patient information, however, identifiable information will be required in order to undertake the linkage.

In order to complete the further work, this amendment also sought to extend the duration of ‘s251’ support until 30 September 2025.

This amendment also sought to change the chief investigator from Professor David Gunnell to Dr Becky Mars, as Professor Gunnell has now retired. Dr Mars was the researcher who worked on the original proposal and is therefore perfectly placed to take this work forward.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair’s Action. The Alternate Vice-Chair was content to recommend support for this amendment to extend ‘s251’ support to cover the processing of confidential patient information of ALPSAC participants, during linkage to GP data, that is already undertaken for main ALSPAC. The Alternate Vice-Chair agreed with the rationale to include primary care data, and noted that the change is reflected in the patient notification documents.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 22/23 DSPT reviews for **University of Bristol (ALSPAC), Swansea University (UK Secure eResearch Server, UKSeRP) & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 09 November 2023)

   Due to the number of participating GPs involved it is the responsibility of University of Bristol, as controller, to ensure that participating GPs 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 an organisation.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed no REC review required by email 06 November 2023**

21/CAG/0121 – Long-term risk of cancer and general health outcomes in women who underwent assisted reproductive technology in Great Britain, 1991-2010: a data linkage study

Name	Capacity
Dr Tony Calland	Chair
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow NHS England to link confidential patient information from the archived ART Cohort dataset, held by NHS England, to the Cancer Registration Dataset and HES.

In this amendment the applicants seek to make two changes to the application.

The first is to remove the control cohort from the women's cohort. In the original application, the applicants had stated the intention to include a control cohort,

comprised of two population controls per each patient who received ART, who would be identified by NHS England. NHS England have advised that they are no longer able to identify the control cohort. The control cohort will no longer be included and only data for patients who received ART will be collected and linked.

The applicants also seek to use data collected for 21/CAG/0121 in the UK arm of the Cancer risk after medically assisted reproduction – An international study-level meta-analysis (CREATE) study. The aim of the CREATE study is to investigate the risk of cancer in women who undergo ART treatment and the children born as a result. The applicants seek to link confidential patient information for a cohort of children conceived via ART, their naturally conceived siblings and a matched control cohort of naturally conceived children, already collected under ECC 4-03(g)/2012. The applicants seek support to link this cohort to the National Cancer Registration and Analysis Service database at NHS England. Linkage of the archived ART Cohort dataset to the Cancer Registration Dataset and HES will also be undertaken and support is already in place for this under 21/CAG/0121. NHS England will disclose a pseudonymised dataset to UCL, where the dataset will be linked via the study ID to pseudonymised fertility data collected for the ART cohort.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advisory Group Chair. The Chair was content to recommend support for the removal of the control cohort and the linkages to under work for the CREATE study.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 22/23 DSPT review for NHS England was confirmed as ‘Standards Met’ on the NHS England DSPT Tracker (checked 11 October 2023) 2.

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 07 November 2023.

22/CAG/0051 – Our Future Health

Name	Capacity
Dr Tony Calland	Chair
Dr Murat Soncul	Alternate Vice Chair
Professor Lorna Fraser	CAG Expert Member
Dr Pauline Lysesight-Jones	CAG Lay Member
Ms Rose Payne	CAG Lay Member
Ms Katy Cassidy	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

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, an 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 and then to 20 million.

The amendment increasing the number of patients to 20 million was supported with the condition that any further amendments needed to provide details on the 6 issues below. The applicants now seek to send invitations to a further 5 million patients.

Confidentiality Advisory Group advice

The amendment request was considered at a Sub-Committee meeting of the CAG on 06 November 2023.

The CAG commended the applicants on the level of detail provided on the work to explore alternative methods of contacting patients and noted that this could have important information for future studies by other researchers. CAG would support this work being made available via the OFH website.

The CAG agreed that the conditions set out in the previous amendment outcome had been met. Namely these were:

a) 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.

The applicants explained that the data collected will enable research to be carried out into the understanding of diseases, and the improvement of population health by advancing diagnostics, prognostics, prevention and intervention.

So far, 409,000 invited participants have attended blood pressure and cholesterol check and have provided a blood sample. Direct participant benefits include that over half of the participants had high cholesterol and 1 in 4 had high blood pressure. Participants have also been alerted to significant cardiovascular issues identified at their OFH clinic appointment.

Members noted that OFH had recently featured in the national press with findings that supported the public benefit of the project.

The CAG noted the information provided and raised no further queries.

b) 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.

The applicants noted that the conversion rate is currently low as some participants are still going through the recruitment process. Details were given on recruitment and conversion rates. The applicants also advised that, following a pilot, they planned to offer financial reimbursement to participants.

The CAG noted the information provided and raised no further queries.

c) 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.

The applicants advised that use of the electoral roll is not a viable alternative as the Open Register, after the removal of opt-outs, only includes 31% of the population. The full register is only available to certain bodies and the OFH does not qualify for access.

Use of commercially available information via Royal Mail had been explored in pilot studies. Pilots were initially conducted in Grimsby, an area not previously included in recruitment, and Stoke on Trent, where DigiTrials invitations were issued in parallel. There was no significant difference in recruitment per letter, but further analysis showed significantly higher response rates to DigiTrials invitations for those under age 40 years and those in the lowest two IMD quintiles. Further pilots were conducted in Portsmouth and Southampton where non-personalised letters were sent, and response rates compared with the use of DigiTrials letters sent to the same area at a different time. The results of the pilots showed that the DigiTrials route performed better at every stage and recruitment rates for the under age 40 years group showed a significant increase in response when receiving a DigiTrials invitation compared to a non-personalised letter.

The CAG noted the information provided and raised no further queries.

d) Evidence of why Digitrials is the only way increased representation of traditionally under represented groups can be achieved.

The applicants explained that Our Future Health is designed to be reflective of the UK population. The applicants provided figures comparing recruitment to Our Future Health with recruitment to other large UK prospective cohort studies. These demonstrated that Our Future Health was successfully recruiting non-white participants and those living in areas with high deprivation, which are generally underrepresented in research studies.

The applicants advised that 77 - 79% of current participants were invited by a DigiTrials invitation and noted that the data supported the hypothesis that use of DigiTrials increased the recruitment rate. The applicants also noted that this figure was likely to be an underestimate, as not all patients would use the URL or QR code provided in the letter to access to OFH website (page 3 of the amendment request).

The CAG noted the information provided and raised no further queries.

e) The effectiveness of the media campaigns to gain the interest of the population, and any changes that have been made as a result.

The applicants used a multi-channel approach to increase awareness of OFH to potential participants, the wider public, local, regional and national stakeholders, and the media. This included national and local print, digital and

broadcast media, social media and public engagement events. Information on the community and regional engagement undertaken was also provided, however assessment of the effectiveness of these campaigns was primarily limited to increase in followers/likes on social media platforms.

OFH adapt their digital advertising based on the weekly reports from their advertising. These included changing the format of information, messaging and campaign objectives.

The CAG noted the information provided and raised no further queries.

f) 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.

The applicants provided details on the patient and public involvement undertaken. The applicants had commissioned a large-scale Public Attitudes Survey to test the public's views on topics including access to patient data and invitation strategies, gaining 1339 responses. The majority of those surveyed were not participants in Our Future Health.

Whilst the survey gained broad support to being invited by letter, and also by personalised letter, it is not apparent if the survey clarified what is meant by personalised letters and how patients' personal information may be used. For example, it does not clarify the difference in how their data may be used if a personalised letter is sent by their GP (where their information is not shared) versus the DigiTrials method where their name and address was sent to an approved mailing company. Members agreed that further patient and public involvement, addressing this specific issue, needed to be undertaken.

The Group agreed that the amendment to increase the number of participants by 5 million should be supported.

However, members agreed that the patient information materials sent to patients via DigiTrials needed to explain how patients' names and addresses had been collected under s251 support.

Members also agreed that the patient and public involvement carried out had not included discussion around the processing of confidential patient

information required to facilitate sending of personalised letters. Further patient and public involvement needed to be conducted, including discussion of this specific question.

The revised patient notification materials and feedback from the further patient and public involvement needs to be provided at the next annual review, due by 29 March 2024.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. The patient information materials sent to patients via DigiTrials needed to explain how patients' names and addresses had been collected under s251 support. The current materials are to be provided at the next annual review.

2. Further patient and public involvement needs to be conducted, which includes discussion of the processing of confidential patient information required to facilitate sending of personalised letters. Feedback is to be provided at the next annual review.

3. 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 2022/23 DSPT review for APS Group Ltd was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 24 October 2023)

4. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed.

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

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
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. No support is currently in place for any patient data to be linked to outcome data, as patients are included in the SLSR with consent.

This amendment sought ‘s251’ support to allow linkage with NHS England data on mortality (date and cause of death) and Hospital Episode Statistics (HES) for all SLSR patients who are either deceased or who had their last follow-up contact with the study team more than 5 years ago. This is because the consent material prior to April 2022 did not mention a linkage with NHS England, and consent material between April 2022 and now only mentions linkage for mortality but not HES data. This amendment was requested by NHS England. After an initial review of the application by NHS England the following conditions for the linkage have been set:

- Applicants will update all patients in active follow-up of the data linkage by newsletter and updated study website, explaining the content and rationale of the linkage and providing contact details in case participants wish to opt out. This process has been discussed and was regarded as appropriate by the PPI group.
- For SLSR participants who are either deceased or who had their last follow-up contact with the study team more than 5 years ago, NHS England require ‘s251’ support to link to mortality and HES data and provide this data back to the applicant.

Applicants have submitted an amendment to REC for the consent materials moving forwards to include HES data linkage (as well as the already included mortality data), and are awaiting REC approval for the use of those documents going forward. The majority of the study cohort (with stroke events dating back to 1995) are deceased, and

a significant number are lost-to-follow-up (applicants undertake regular follow-ups up to 15 years post-stroke) and can therefore not be re-consented to this new data linkage.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs Action. The Chair recommended support for the amendment, noting that reconsenting is expensive and will inevitably lose a significant number of patients through non response. This is an important register addressing a major cause of morbidity and mortality so there is both a medical purpose and public interest in this amendment going ahead.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 22/23 DSPT reviews for **Guy's and St Thomas' NHS Foundation Trust (RJ1) and King's College Hospital NHS Foundation Trust (RJZ), King's College London - School of Population Health & Environmental Sciences - South London Stroke Register (EE133874-SPHES-SLSR) & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 11 October 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 18 October 2023**

PIAG 1-05 (j) 2007 - A national population-based case-control study of the genetic, environmental and behavioural causes of breast cancer in men

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This amendment sought support to change the Chief Investigator from Professor Richard Houlston, to Professor Montserrat Garcia-Closas, as Professor Richard Houlston was interim CI until ICR appointed a new Professor of epidemiology.

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 **22/23** DSPT review for **The Institute of Cancer Research was** confirmed as 'Standards Met' on the NHS England DSPT Tracker (confirmed by email 03 November 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 02 October 2023**

22/CAG/0147 – A Randomised Phase III Trial to Determine the Role of FDG-PET Imaging in Clinical Stages IA/IIA Hodgkin's Disease (FDG-PET Study): RAPID

Name	Capacity
Ms Clare Sanderson	CAG Alternate Vice Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to compare the late consequences, especially vital status, second cancers, and cardiovascular disease, of the different treatments used in the RAPID trial with a view to informing future patients and guiding national/international treatment policy.

's251' support was originally in place for The Christie to link the datasets and provide access to the statistician at UCL, who will then analyse the data at The Christie, within their servers.

This amendment sought support for the Christie to disclose confidential patient information (inclusive of date of death) for analysis to the statistician at UCL.

Transferring the data to UCL CTC for analysis will ensure that all RAPID analysis is consistent. It will allow the study statistician to use exactly the same software (installed at UCL) that has been used for all previous RAPID analysis. Prior to the request for this extra data flow to be included, applicants had planned for the statistician to analyse the data remotely on the Christie servers. However, upon setting up access to facilitate this, it has become apparent that this is not optimal.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Alternate Vice-Chair was content to recommend support for 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 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 22/23 DSPT reviews for **The Christie NHS Foundation Trust, University College London – School of Life and Medical Sciences, NHS England** & on behalf of NICOR**; NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM) and Redcentric (Harrogate)** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 17 November 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 15 August 2023**

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. Short title: UK and Republic of Ireland Neonatal Stroke Surveillance

Name	Capacity
Ma Caroline Watchurst	Confidentiality Advisor

Context

Amendment request

This application from University of Nottingham aims to determine the number of new cases of Neonatal stroke in the UK and Republic of Ireland over 13 months, as well as determining the proportion of neonatal stroke subtypes.

This amendment sought support to include Amazon Web Services as an additional data processor for the application. The University of Dundee Health Informatics Centre (HIC) will be migrating their servers to Amazon Web Services cloud. The front end of the system will remain the same however this migration will mean safe haven and back end data will be migrated and sit on a Trusted Research network (TRE) as opposed to being stored by Bright Solid on the Safe haven on Prem (the existing safe haven software). The HIC Safehaven are still the main data processor storing the information, and the data is still being stored in the UK and managed by them. However, they are just moving the physical location of the data from onsite servers to AWS cloud storage which offers better security. The cloud service still have ISO27001 certification.

This amendment also sought support to clarify that where data collection via other agreed pathways is not possible, the study team will liaise with the reporting clinician directly to obtain the clinical information which will be entered by the research team directly onto the HIC Safehaven. The rationale for offering more than the online questionnaires and NHS email option is because it is recognised that some clinicians do not have an NHS email account and therefore utilising NHS to NHS email only with

password protection is likely to result in under ascertainment of cases as they will not be reported. This study relies on getting accurate numbers of cases to ascertain an accurate incidence and this is likely to pose a barrier to achieving this. This has also been standard BPSU practice for over 120 studies.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 **22/23** DSPT review for **University of Nottingham E133856-RGD** was confirmed as '**Standards Met'** on the NHS England DSPT Tracker (confirmed by email 27 October 2023)

   The application also has PBPP approval in place to evidence security assurance to CAG regarding processing by University of Dundee.

   Security assurances are required for the submitting clinicians. Support will be based on confirmation that the DSPT at the site will be complied with. However, as this is 5 or more organisations, these will not be individually

checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 23 October 2023**

CR4/2014– Asbestos Workers Survey

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the Health & Safety Laboratory monitors the long-term health of asbestos workers and helps to determine whether the 1969 Asbestos Regulations were effective in reducing the risk of asbestos-related ill-health. This study had previously accessed data under the NHS Central Register (ECC 2-04(c)/2010) application.

Support is currently in place to cover access to mortality and cancer data from the NHS Central Register, maintained by NHS England (previously NHS Digital, and prior to that - the Health and Social Care Information Centre - HSCIC), and to confidential patient information including name, address, date of birth and NHS number. A cohort of approximately 100,000 patients as of 2006 had been flagged at NHS England. The cohort size was projected to continue to grow by approximately 2,000 per year, but participants from 2006 onwards had provided consent and are therefore not included within support given under the Regulations.

This amendment sought support for a change in Chief Investigator for the application. The current Chief Investigator, Lucy Darnton, was appointed on a temporary basis when the previous Chief Investigator retired. Gillian Nicholls, Principal Epidemiologist at the Health and Safety Executive, has now been appointed as the permanent Chief Investigator.

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 **2022/23** DSPT reviews for **Health and Safety Executive Laboratory** & **NHS England** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 12 October 2023).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 23 October 2023**

20/CAG/0084 – PIONEER

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

Context

Amendment request

This application has 'support to allow transfer of confidential patient information from West Midlands Ambulance NHS Trust to University Hospitals Birmingham NHS Foundation Trust to establish the PIONEER research database.

The PIONEER team now wish to supplement this information by adding Birmingham Community Healthcare NHS Foundation Trust (BCHC) as an additional data source. Confidential Patient Information will be shared and linked with existing information in the same manner as West Midlands Ambulance NHS Trust. Doing so will enable evaluation of projects on providing more care in peoples' homes after an acute presentation to hospital.

As part of this amendment the applicant also provided a detailed report on the current successes and issues identified with the current reidentification and linkage processes. This was as per Condition 1 of the original outcome letter dated 28 September 2020, which was to be submitted on addition of the next external organisation.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair considered the amendment was reasonable and was supportive of the request to add a new site.

The Chair also thanked the applicants for the detailed report and agreed that continuation of the current linkage processes seemed reasonable.

The Chair noted that conditions 2 and 3 from the original outcome letter remain for this Trust, as set out below.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Support is limited to the use of structured data and unstructured medical image data only.

2. Support is not provided for the use of unstructured free text data. Where the applicants wish to use this form of data in the future, a detailed amendment/paper should be submitted to the CAG, providing information on

how the applicants have considered the pseudonymisation methods of free text data at source, and how they demonstrate its effectiveness in deidentification.

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: **Confirmed**

   The NHS Digital **22/23** DSPT reviews for **University Hospitals Birmingham NHS Foundation Trust**, **West Midlands Ambulance Service NHS Trust** and **Birmingham Community Healthcare NHS Foundation Trust** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (confirmed by 21 November 2023)

4. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed (REC considered no review required)**

16/CAG/0043 – British Association of Dermatologists Biologic Interventions Register

Name	Capacity
Ms Caroline Watchurst	Confidentiality Advisor

Context

Amendment request

This amendment sought support to amend the Chief Investigator (CI) for the study. Following the retirement of Professor Chris Griffiths, Professor Richard Warren has taken CI responsibility.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. No concerns were raised.

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 22/23 DSPT reviews for **University of Manchester & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 24 November 2023)

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

22/CAG/0103 – Supporting the NHS Long Term Plan: An evaluation of the implementation and impact of NHS-funded tobacco dependence services

Name	Capacity
Ms Caroline Watchurst	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow research staff at participating trusts to access confidential patient information in order to identify eligible patients and extract a pseudonymised dataset. Hospital records will be accessed to determine the number of smokers who have been offered and used tobacco dependence services and to calculate the cost of providing the service.

This amendment sought to extend the duration of 's251' support, as the funding organisation (NIHR) has provided a 3-month no cost extension to the project, resulting in the new project end date moving from 31st December 2023, to 31st March 2024.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team 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 organisations involved it is the responsibility of Newcastle University, 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 about an organisation.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 30 October 2023**

19/CAG/0173 – Critical illness related cardiac arrest (CIRCA): an investigation of the incidence and outcome of cardiac arrest within Intensive Care Units in the United Kingdom.

Name	Capacity
Ms Caroline Watchurst	Confidentiality Advisor

Context

Amendment request

Support is currently in place to allow disclosure of confidential patient information from participating intensive care units to Intensive Care National Audit and Research Centre (ICNARC) to facilitate linkage with the National Cardiac Arrest Audit and onward disclosure to NHS England (previously NHS Digital) to facilitate linkage with HES and ONS datasets, for the research purpose of gaining a wider understanding on prevalence and outcomes of patients who experience cardiac arrest whilst in an intensive care unit.

This amendment is to extend the duration of support required until 7 October 2024. The study has been delayed, and the extension is required in order to complete analysis.

The website will be updated with new study timelines.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries with 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 22/23 DSPTs for **Intensive Care National Audit and Research Centre (ICNARC) & NHS Digital have been confirmed as 'Standards Met'** by NHS England (Confirmed by check of DSPT tracker 24 November 2023).

   Due to the number of organisations involved it is the responsibility of Intensive Care National Audit and Research Centre (ICNARC), as controller, to ensure that Trusts meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a Trust.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 31 October 2023**

23/CAG/0022 – Infant Feeding Survey 2023

Name	Capacity
Ms Caroline Watchurst	Confidentiality Advisor

Context

Amendment request

The 2023 Infant Feeding Survey has ‘s251’ support to allow NHS England to use confidential patient information to link patients identified from the Maternity Services Dataset (MSD) to the Personal Demographics Service to identify the most up to date contact details, and to allow the disclosure of confidential patient information from NHS England to IPSOS UK (for the purposes of sending questionnaires, and for analysis), and then onwards to Formara Ltd and Gov.UK Notify, for the purpose of sending out questionnaires for the 2023 Infant Feeding Survey.

The cohort described in the initial CAG outcome letter is: Mothers aged 16 years or over at the time of delivery, who gave birth under the care of an NHS trust (including home births), in a given month (specific month contingent on the DARS processing times). Approximately 26,483 people will have invitations sent.

This amendment is to clarify that the ‘s251’ support covers both a pilot study and a mainstage study, and therefore the cohort will be drawn as 2 data extracts from August 2023 (pilot) and December 2023 (mainstage). The cohort size will not widen or increase, and applicants will send out the same number of invitations as stated in the CAG application (26,483). The pilot will see 10% of this amount (2648) receive an invitation to participate, and the mainstage will see the remaining amount receive an invitation to participate (23,835).

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 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 **22/23** DSPT reviews for **NHS England, Ipsos UK, Formara Ltd, the Department of Health and Social Care (which covers GOV.UK Notify Service)**, **and TextLocal Ltd** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (09 October 2023)

3. Annual Review Approvals

CAG reference	Application Title
CAG 5-07(d)/2013	National Emergency Laparotomy Audit
16/CAG/0043	British Association of Dermatologists Biologic Interventions Register (BADBIR)
22/CAG/0001	RECAP (Remote Covid Assessment in Primary Care): a learning system approach to develop an early warning scorefor use by primary care practitioners
ECC 3-03(c)/2012	Manchester Cancer Research Centre Biobank – collection of tissue, blood and urine for cancer research
18/CAG/0071	Avoiding Cardiac Toxicity in lung cancer patients treated with curative-intent radiotherapy to improve survival
PIAG 3-07(j)2002	Study into the long-term consequences of chronic diseases and their treatments
14/CAG/1012	NIHR Critical Care Health Informatics Collaborative
19/CAG/0136	Acute Leukemia in Pregnancy Registry Study
22/CAG/0062	A study of Cardiovascular events iN Diabetes - PLUS

19/CAG/0195	STRETCHED: Strategies to Manage Emergency Ambulance Telephone Callers With Sustained High Needs - An Evaluation Using Linked Data
22/CAG/0092	Establishing evidence to inform culturally competent mental health services (EVOLVE)
21/CAG/0020	The effect of age at first invitation for breast screening in the NHS Breast Screening Programme in England and Wales (AFBSS)
22/CAG/0119	CLUSTER JIA-uveitis research database
19/CAG/0172	SEARCH: A population based study of genetic predisposition to breast, OVARIAN & endometrial cancer
18/CAG/0142	SEARCH: A population based study of genetic predisposition to breast, OVARIAN & endometrial cancer
19/CAG/0171	SEARCH: A population based study of genetic predisposition to BREAST, ovarian & endometrial cancer
21/CAG/0137	IBIS II O: Long term observational follow up of previous participants of the IBIS II studies: DCIS and Prevention
21/CAG/0127	The Oxford Vascular Study: (OxVasc)

Signed – Chairs	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Professor William Bernal, & Dr Murat Soncul, CAG Alternate Vice-Chairs	*14 December 2023*

Signed – Confidentiality Advice Team	Date
Caroline Watchurst, Confidentiality Advisor	*11 December 2023*