Health Research Authority

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

June 2023

1. New Applications

a. 23/CAG/0029 – Catch-up Screen: A urine test for cervical screening

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice Chair
Dr Martin Andrew	CAG Member
Dr Pauline Lyseight-Jones	CAG Member
Ms Rose Payne	CAG Member
Mr Dan Roulstone	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from the London School of Hygiene & Tropical Medicine set out the purpose of medical research that seeks to measure patient response rates, HPV

prevalence and histological outcomes among older women to estimate the likely impact on cervical cancer incidence and mortality of introducing a nationwide catch-up screening programme.

The NHS Cervical Screening Programme (CSP) prevents an estimated 5000 deaths per year by offering regular cytology screening. HPV screening has replaced cytology in many countries, including in the UK. Currently, screening in the UK is stopped at 65 years of age, which is unchanged since the introduction of the screening programme in 1988. Australia offer HPV screening up until the age of 74 and Denmark offer screening to all women born before 1948. Most cervical cancers in young women are diagnosed at stage 1 but the proportion diagnosed at stage 2 or worse increases with time since last screening test, and the ratio of mortality to incidence increases after age 65 when cytology screening stops. The justification for ceasing screening at 65 is that it is unlikely that women aged over 64 years who have been regularly screened will go on to develop the disease. However, around 1 in 1200 women who were regularly screened after 50 years of age and 1 in 230 women who were unscreened after age 50 to develop cervical cancer after the age of 65. Around half the relevant population were either unscreened or inadequately screened after age 50. The applicants seek to offer a catch-up HPV test, via a urine test that patients can do at home and use the results to measure response rates, HPV prevalence and histological outcomes to estimate the likely impact on cervical cancer incidence and mortality of nationwide introduction.

Support is sought to enable researchers, who are not part of the direct care team, to access patient records at participating GP practices in order to identify and make contact with eligible patients. Support is also required to allow the extraction of confidential patient information from GP practices and transferred to NHS England for linkage to cervical screening record, current status, and registrations of cancer and death. Patients NHS number and date of birth will be removed before the linked dataset is transferred to the London School of Hygiene & Tropical Medicine. GP practice data and the linked dataset will be linked via the study ID.

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

Confidential patient information requested

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

Cohort	Women aged 60 – 79 years of age who ceased from the NHS CSP without an exit primary HPV test. 18000 women will be included.
Data sources	1. Patient records at participating GP practices 2. NHS England DARS for current patient status, cancer registration and mortality from national registers and the NHS Cervical Screening Programme (Open Exeter).
Identifiers required for linkage purposes	1. NHS number 2. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – unit level 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice

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

1. **Provide the names of the GP practices participating in the study.**

The pilot GP practice had been identified as James Alexander Family Practice in Hull. The applicants were working with Greater Manchester and Yorkshire & Humber CRNs to identify suitable GP practices for the study.

The CAG noted that amendments would need to be submitted once additional participating organisations had been identified.

2. **The patient notification materials need to be updated to state that patients confidential patient information will be processed without consent unless a patient specifically objects.**

A revised patient information booklet and GP practice “opt out” poster were provided.

Members noted that there are likely to be time constraints on when individual patients could opt-out and asked that this was highlighted more clearly in the booklet and poster.

Members also asked that the booklet was revised so that the required information about opt-out was more prominent.

The applicants provided a poster and booklet, revised to advise patients to opt-out as soon as possible. If a patient calls to opt-out, our researcher will explain exactly what aspects of

their data have already been processed and the options open to them to have their data removed. The applicants had also added a sentence to the section on page 2 entitled “What happens if I do not want to take part or change my mind?” Bold format had also been used under the “Data Confidentiality” section as suggested by CAG.

The CAG noted these changes and raised no further queries.

3. **Clarify if further patient and public involvement, with a larger group, is planned.**

The patient and public involvement group had reviewed the updated notification materials. No concerns were raised about the documents.

The applicants planned to conduct further patient and public involvement as the study progresses and will actively seek additional feedback from patients invited from the pilot practice. The protocol involves follow-up phone calls this call will be used as an opportunity to assess whether the documents are clearly understood. Feedback from the pilot practice will be noted and any changes recommended will be made prior to launching the study in further GP practices.

The CAG requested further details on the patient and public involvement to be conducted. The applicants advised that, during the pilot phase, where 3,000 women will be invited to take part, half will be randomised to receive a phone call shortly after their invitation pack is sent. This opportunity will be used to seek feedback from a larger number of women. The feedback will be used to make amendments as required. All women will be invited to ask any questions they may have about the study and specific feedback from the first 100 women in the pilot practice will be sought.

The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Favourable Opinion issued 16 January 2023**

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

   The NHS Digital **21/22** DSPT reviews for **London School of Hygiene & Tropical Medicine** and **NHS England** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 March 2023).

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

b. 22/CAG/0171 - Ambulance Data Set – Returning linked patient outcome data to Ambulance Services

Name	Capacity

Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Professor Lorna Fraser	CAG member
Ms Diana Robbins	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application from NHS England, sets out the purpose of providing a flow of linked Emergency Care Dataset (ECDS) and Ambulance Data Set (ADS) data back to the to the eleven English Ambulance NHS Trusts to inform individual clinical development plans and wider Ambulance Service operational and clinical improvement strategies.

There is a legal direction in place to flow data collected by Ambulance Trusts to NHS England (previously Digital), to create the ADS. Additionally, this legal direction covers linkage between ECDS and ADS, which is already undertaken and does not require 's251' support. Separately to the flow of data to Ambulance Services, under the joint NHSE/NHSD commissioning arrangements, the NHS England and NHS Arden & Gem CSU (DSCRO) is also able to receive and link identifiable patient information (ADS data) with other datasets, (e.g. ECDS) and apply its own pseudonymisation key before flowing the data to the National Commissioning Data Repository (NCDR) (a web based application developed by Arden & GEM CSU on behalf of NHS England). This is out of scope for this application. The only element of the application that requires 's251' support is an identifiable flow of linked data from the DSCRO to the 11 ambulance Trusts. The only identifiers used are CAD ID and call sign, so that the patient outcome can be linked to the initial treatment episode. NHS Digital have confirmed 's251' support is required for this flow, as the ambulance Trusts will be able to re-identify the patient using the CAD ID and call sign.

The ambulance services provide care to 25,000-40,000 patients per day. These organisations are publicly funded and there is a moral and fiscal responsibility to ensure that these services are allocating their resources appropriately. A major barrier to this is that resources are allocated based upon predictions of what type of care a given patient will need, however there are no reliable means by which this prediction can be

correlated with the actuality of the care needed. It is therefore important to be able to review resource allocation and care provided in the context of further care provided once a patient is admitted to hospital. This application will use linked outcome data to analyse patterns, which will aim to inform development needs and best practice identification.

Once received into each of the 11 Ambulance Services, the ECDS data will be kept in a separate table within data warehouses so won't form part of the main patient record, but by holding the data CAD ID and Call Sign this will enable linkage to the existing patient record. The CAD ID and Call Sign will be retained in this separate table to ensure that the correct episode of care is linked in cases where there are multiple patient contacts over a short period of time. These records will be managed in line with the national NHS data retention policies.

Regarding informing individual clinical development, the provision of linked data will allow ambulance service clinicians to continue to build on their confidence, competence and knowledge to improve the delivery of care to patients through the understanding of the impact of their own clinical practice on the patient outcomes through the clinical supervision process. Benchmarking clinician activity will also allow understanding of where additional skills development and mentorship is available; whilst reflective practices are helpful for clinicians, understanding of their performance on an aggregated level against their peers will support targeted training interventions. Benchmarking clinician activity and involvement in point of care delivery will allow understanding of the following examples:

- Where clinical skills have been delivered for patient benefit and where opportunities may exist to improve (e.g. gaps in skill set offered, gaps in individual practice and where mentorship, clinical supervision or additional practice support would be beneficial)
- indicators, aggregated peer or team data and other KPI or regulatory requirements.
- Monitoring of clinical care given to patient cohorts and the development of evidence-based practice/interventions for patient benefit
- Inform wider work on service delivery model evolution
- Inform the management of complaints, potential serious incidents or other enquiries that relate to clinical care delivery by clinicians

Regarding wider Ambulance Service operational and clinical improvement strategies, Business Intelligence Teams will be able to undertake pattern analysis to understand if clinical behaviours are consistent for patient cohorts and across treating clinicians, as well as treatments administered by the Ambulance Service. This will allow organisational planning and ensure that patient presenting with similar conditions and requirements are receiving interventions and treatments that consistently best meet the needs of patients. The application will support the identification of gaps in provision at a local level, and will provide a stronger evidence base to work collaboratively with commissioners understand where changes to patient pathways within particular areas would benefit patients and reduce pressure on busy Emergency Departments (ED), one of the key areas of interest from Health Ministers and the Secretary of State.

For example, by linking the diagnosis to the presenting symptoms, the ambulance Trusts will be able to identify better systems for identifying those conditions which require urgent medical attention and refer future patients to the correct care pathway, e.g. stroke and cardiac arrest. Likewise, if Ambulance Trusts are able to identify that certain subsets of patients with the same patterns of presenting symptoms are often not admitted to hospital or discharged very quickly, then A+E attendance could potentially be avoided for future patients presenting with those symptoms, which would benefit all parties, including the patient.

The pattern analysis will support senior leadership to understand if operational practices and systems are consistent for patient cohorts and clinicians. Some examples are below:

- Understanding patient destination following conveyance, and if it differs from the ED to inform service and pathway development (e.g. where a patient is conveyed to ED but then direct streamed at ED triage to another co-located service or department).
- Patients conveyed by Ambulance Services with time critical and time sensitive illness are prioritised for care and handover accordingly
- Treatments or therapies that may be administered by ambulance service that could be improved or changed
- Understanding of any simple assessments, treatments and other investigations that can be ‘front loaded’ to optimise subsequent assessment

and treatment of Ambulance patients e.g. where there are Ambulance handover delays.

- Identify opportunities for service improvement, operational efficiencies, and shared governance to inform better working for patient benefit

There is no intention to share individual level data outside of the ambulance services e.g. with commissioners, although summary outcomes of the data analysis may be shared to inform commissioning of care pathways and service improvements. The outputs will be made available in aggregated form through internally developed dashboards and data insights platforms for senior leadership teams within Ambulance Services to understand the current position and commission policy development to improve patient care. These dashboards will not disclose any personalised patient information.

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

Confidential patient information requested

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

Cohort	All patients in contact with any of the 11 English Ambulance Services listed below, who go on to receive care through an NHS Provider that completes an Emergency Care Record through the Emergency Care Data Set (ECDS) and flows to NHS Digital. Approximately 5 million patients per year
Data sources	1. NHS England (previously NHS Digital) – a. Ambulance Data Set (ADS) collected from the following 11 Ambulance Services: i. East Midlands Ambulance Service

	ii. East of England Ambulance Service iii. Isle of Wight Ambulance Service iv. London Ambulance Service v. North East Ambulance Service vi. North West Ambulance Service vii. South Central Ambulance Service viii. South East Coast Ambulance Service ix. South Western Ambulance Service x. West Midlands Ambulance Service xi. Yorkshire Ambulance Service b. The Emergency Care Dataset (ECDS) collected from acute NHS hospitals.
Identifiers required for linkage purposes	• linkage between ADS & ECDS is undertaken with alternative legal basis • Linkage between ECDS and ambulance Trust clinical record; 1. ADS 3 Call Identifier –CAD ID (Unique number generated within the Ambulance Service 999 Operations Centre) - (direct identifier) 2. ADS 36 Call Sign - (Unique vehicle reference of ambulance service) (direct identifier)
Identifiers required to be returned to individual ambulance Trusts for analysis purposes	1. ADS 3 Call Identifier –CAD ID (Unique number generated within the Ambulance Service 999 Operations Centre) - (direct identifier) 2. ADS 36 Call Sign - (Unique vehicle reference of ambulance service) (direct identifier) 3. ECDS 20.1 Diagnosis 4. ECDS 21.1 Investigations 5. ECDS 22.1 Treatments 6. ECDS 23.1 Referred to Services 7. ECDS 24.2 Discharge Status 8. ECDS 24.4 Discharge Destination 9. ECDS 24.5 Discharge Info Given 10. ECDS Emergency Care Departure Time
Additional information	Ambulance Services will only receive data that pertains to records that were initially generated within their service

	It is proposed that this data will flow to Ambulance Services on no more than daily basis using linked data in arrears (e.g. Monday will flow the previous Monday) However, due to resource capacity and funding, delivery of the technical requirements can only be scoped and formally started following confirmation of 's251' support to the application. It is anticipated that the technical requirements could allow for scheduling of data sharing to able to be shared on a daily basis with a rolling 7-day time delay, so each day, data would flow for the same day of the previous week. However, if through development there is a technical/resource issue identified applicants may look to reduce the frequency of data flows to mitigate any technical challenges.

Confidentiality Advisory Group advice

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

1. **Clarify how the data will be used in the 'management of complaints', noting that CAG would not expect the data to be used in the investigation of individual complaints.**

The applicant confirmed that in the case of individual complaints, the data will be used according to the stated use cases: only if the complaint and / or Serious Incident (SI) have identified a clinical need for learning, the data will be used as an opportunity for structured learning for the clinician involved as part of the Clinical Supervision Framework. Understanding patient outcomes in patient safety related complaints in a controlled and structured way would be one part of a much wider process of individual incident learning, reflection on decisions made at clinician level and wider organisational learning. Existing processes for management of complaints are in place and will not be affected by returned ECDS data. The CAG were content with this response.

2. **Provide absolute clarity on whether the returned data is being linked and included into the main clinical record.**

The applicant confirmed that the returned data from ECDS will not be added to the main clinical record – however the CAG queried some wording surrounding apparent provisos such as: '- *most* outputs will not be patient identifiable,' '- *primarily* in aggregate or non-identifiable form.'. The applicant was asked to clarify any times when confidentiality would not be assured, and in a secondary response confirmed that data will not be used or accessible in identifiable format and datasets will be created and used in aggregated or non-identifiable form, for use cases such as alternative pathways development. The use case for individual clinicians learning and development will require the data to be identifiable, in order for cases to be reviewed and support additional learning and improved clinical practice as part of an individual clinician's clinical supervision, however identifiable data will only be accessible to the individuals who attended the patient, and their clinical supervisors/managers, ie. the direct care team. None of the data will be shared outside of the Ambulance Service to other organisations other than in aggregated form. The CAG were content with this response.

3. **Confirm what format the databases will take at each Ambulance Trust. Will these contain linked baseline data, and if so, what data?**

The applicant confirmed that the linked ADS+ECDS data will flow into a data table within a relational database as part of each Trusts' data warehouses which is a high security-controlled access platform, rather than an accessible database. Ambulance service data warehouses hold other data, including electronic patient records (EPR), Computer Aided Dispatch (CAD) and other bespoke systems used within the ambulance services.

Data are linked by technical staff, such as analysts or developers in order to generate dashboards/reports/analysis for analysis, and to provide outputs for users. All data items from within a table are not visible, only those data items required from within for the purpose of the report/dashboard. Users can only see the selected fields in outputs. The Sub-Committee were content with this response, after the clarification in point 2 with regards to identifiable outputs.

4. **Confirm who will be able to access the separate databases. i.e. is access restricted to only when a clinician is in supervision? Is it only the treating clinician that will have access to the patient, or is it other paramedics who may not have been involved in the care of that individual patient?**

The applicant confirmed that for clinical supervision purposes, data would only be available to the treating clinicians and the clinician leading the supervision. The

additional data items from ECDS would form part of the wider patient dataset already held and discussed as part of their supervision or a case review.

It is not intended that this information would be accessible for clinicians to look up their own cases at individual patient level. Ambulance Services will be directed to create a standard template to provide a personalised output of high-level information for clinicians for use within the formal clinical supervision process, with clinicians able to request specific case details in advance of the meeting. Clinicians will not be able to request information about cases they were not involved in. This applies to all the clinical data already held by the ambulance services, as well as these additional 8 data items matched from ECDS.

A clinical supervisor could request linked data for an individual case for the clinician they supervise if an individual complaint or Serious Incident has shown the need and / or an opportunity for structured learning for the clinician involved. This is in line with the use case proposed for individual clinicians' learning and development. Th Sub-Committee were content with this response.

5. **Provide any information you have on governance surrounding the 11 databases, including access controls and restrictions. The CAG recommend access logs to state who has accessed the database and for what purpose.**

The applicant stated that the data will be held within a secure Data Warehouse, which is highly restricted and fully governed by Trusts IT and access policies. Security is controlled both at a server level where the warehouse resides, as well as for individual relational databases within the warehouse.

All reports or dashboards using the linked data table can be identified systematically, and use of all reports/dashboards is logged and can be viewed by analytical and IT system staff to identify who has run which reports/dashboards, when, and how often, if required.

All access to outputs would be restricted, as required, as part of the release by analytical staff – anything containing personal identifying data (either these linked data items, or other personal identifying information held from the CAD or EPR systems) will always be restricted and access to it managed appropriately for its intended use. There are various ways to do this, such as through role-based access (so access dependant on their job role) or manually only giving specific usernames permissions to access it.

Ambulance Service will be directed to develop a policy, or update existing policies governing data access, to incorporate use of additional patient data not generated within Ambulance Services. This should include how access to this data will be audited and should note the following:

- No clinical colleagues will have direct access to linked patient information - a standardised data extract/report should be developed to be used for formalised clinical supervision purposes. Where specific case details are required, these should be requested in advance of any planned supervisory meetings. This is in alignment with the agreed Clinical Supervision Framework

- Ambulance Services are able to use the data in an aggregated format to develop understanding of outcome activity to share with other stakeholders as appropriate – however this should be at an aggregated locality/service level only, with appropriate data suppression controls applied.

The Members were content with these clarifications.

6. **Regarding the proposed wording to be inserted into the 11 Ambulance Trust privacy notices, CAG strongly recommend harmony between each Trust, and that the wording as recommended by NHS England is not to be altered. Please can you confirm if this is possible.**

Applicants confirmed that the ADS Programme Team have been working with the National Ambulance Information Governance Group (NAIGG), formed by all English ambulance service Information Governance leads as constituent members. The leads have all been consulted on the text of the privacy notices and agreed to publish the unaltered national wording as agreed with NHS England. The ADS team have also consulted patient groups about the wording of the privacy notices to ensure the text is clear and accessible to all service users. As a result of consultation and work with both patient groups and national IG leads from all English ambulance services, the text has been amended and a new iteration drafted. The NHS England recommendation letter to Ambulance Services formalises this as a requirement. The CAG were content with this.

7. **Develop a layered approach to patient notification, including improving the proposed privacy notice text, and developing a more detailed patient notification document that can also be displayed on websites, which is specific to this CAG application, and provide all relevant documents to CAG for review.**

The Privacy Notice text has been amended following feedback from the patient engagement exercise undertaken. In addition to the harmonised privacy notice to be published on ambulance services' website alongside their existing privacy notices, the ADS programme team have worked with communications colleagues at NHS England, the Association of Ambulance Chief Executives (AACE) and with ambulance services communications leads to develop national and local communications to ensure that patients and users of the service are informed and aware of the proposed use of data.

This includes text for ambulance and acute trusts websites, bulletins and intranets and display screens in hospital. The national communications plan and the local ambulance services key messages – including a tactics plan with activities for ambulance services to undertake.

The Sub-Committee reviewed the privacy notices and felt it would help if an easy title was given to this activity which would enable people to recognise the notifications in different contexts - the whole activity could be 'branded' with a simple, descriptive title which would enable people in a waiting room to identify immediately what leaflets/screens are about, However this is a comment not a requirement from CAG.

The CAG commented that the sentence on opting-out (accidentally presented twice in the text) is expressed negatively '- thereby disabling linking…', and doesn't distinguish between the National Data Opt Out (NDOO), and a study specific opt-out. The 'more information' link only leads to the NDOO. The CAG requested the applicant rephrase the opt out sentencing to make the option to opt out a neutral act rather than a negative one, and asked for the applicant to include into the notifications/comms the fact there is a local opt out, and make this obvious as to how to use, to prevent even more people from taking the NDOO option.

The applicant provided an updated notification document, with an updated title. The section on opt-outs has been amended to re-phrase the opt-out option in a neutral manner. Further information about how to opt out of the local process and the NDOO have been separated. However, the contact details for each ambulance service to allow patients to opt out directly with them will be different and dependent on each ambulance service. Applicants will ask ambulance services to insert their own details in the local privacy notices. The CAG were content with the final draft.

8. **Consider if developing posters for A+E is an option, and if so, please provide to CAG for review.**

The applicant informed CAG that the ADS team have worked with NHSE communications colleagues on a wider communications plan. The advice received from communications experts is that display screens to be shown across different settings – e.g. A&E wating areas, GPs reception areas etc. – would be more effective and easier to distribute and display than physical posters.

Due to current pressures, it has not been possible within this timeframe to commission the visual mock-up of a display screen. However, applicants have provided the text to be used for virtual displays. If 's251' support is granted, the communications team will work further on the visual elements of the display screen.

The CAG agreed this is a good idea in principle. However, in practice, they often are not working, and this message would have to compete with all the others on the screen cycle. The draft text provided consists of no title, 3 sentences, no reference to identifiable information, and no reference to opt-out – which the CAG do not feel is useful, however CAG were unclear how much information a display screen can cope with. The CAG note that if it's as little as this, then the display screen communications in Trusts should simply be a sign-post to a poster and/or leaflet. The CAG therefore suggested either improved display screen text, or simple but comprehensive texts for posters and leaflets instead. The CAG however note that this is a Trust decision, so accept that it is difficult to insist.

The applicant responded further with updated text, and commented that Trusts can adapt and adopt key messages to display information in the most appropriate manner. The CAG stated the update provided was satisfactory, and note that the applicant will be further developing the visuals.

9. **Please provide a communications plan that is both national and local.**

The applicant stated that the ADS programme team have worked with the NHS England communications team and with the Association of Ambulance Chief Executives communications team to draft a national communications plan and a communications

pack for local ambulance services. In particular, the local pack has been developed engaging with local ambulance service communications leads, who have had opportunities to provide feedback and are supportive of the pack. This pack includes a tactics plan with activities for local ambulance services to undertake to ensure that the new use of data is sufficiently communicated to users of the service. These two documents are attached as supplementary files. The CAG were content with this response.

10. **Regarding application specific opt out and National Data Opt Out, please confirm if it is possible for the DSCRO to apply opt outs centrally, prior to disclosure. Please ensure the opt out options are clearly stated on all patient notification documents.**

The applicant confirmed that the DSCRO will implement a system that will allow patients to opt out centrally. The details of the process are described in the response. the CAG were content with this.

11. **Undertake further patient and public involvement, with more individuals, maybe as focus groups rather than a survey, that specifically discusses the breach of confidentiality in this application.**

The applicant confirmed that the ADS programme team have set up four different sessions with four separate patient groups. These groups were identified to ensure geographical representation across England and a cohort of users of emergency services. This has coincided with a time of great pressure, with numerous days of industrial action across services, resulting in extensive media coverage on the ambulance services. Despite these pressures on ambulance services in particular, who are key stakeholders in the identification of the cohort, applicants were still able to work with them to bring together groups of patients who are users of emergency services, as patients or carers. The ADS team met with the following groups:

- The Service Users Focus Group of West Midlands Ambulance Service (8 people)
- The Patient Engagement Group of Dorset Integrated Care System (~15 people)
- The Public and Patients Council of London Ambulance Service (~20 people)
- The Patient and Public Panel Group of North West Ambulance Service (8 people)

In total 51 people attended the four focus groups. However, advance pre-meeting materials detailing the proposed use of the data and the changes made were circulated

to over 360 patients in total across the groups inviting them to attend. On the day, this information was also presented at the start of each meeting and the majority of time was left for discussion and input from patients. A copy of the materials presented on the day has been provided. All groups engaged very well with the discussion, showed clear understanding of the issues presented and stated their support for the use of confidential patient information without consent. Applicants have shared relevant feedback, which that applicant states has been taken into account and incorporated, in improving the text of privacy notice and communicating changes to patients. As part of the letter to the Ambulance Service Chief Executives, ambulance services have been asked to further engage with patients in relation to linked data and to provide assurance to the ADS Programme Team. The CAG were content with this response.

12. **Confirm if the separated databases can be anonymised after a year, once linkage between ambulance data and outcome data has been completed, to represent an exit strategy from 's251' support regarding individual patients.**

The applicant stated that this data will not be linked, by default, to other data, in any permanent way. The data table requires the Call Identifier which enables it to be linked to other data as required. The removal of this call identifier from the table after a year would render the information unusable after this time, as it would take away the ability to link it to other data, such as age, gender, hospital attended and other key information that is required to identify patient cohorts, or to monitor changes in practice at clinician and organisation level, and any subsequent benefits, through doing time series analysis. Availability of clinical information over a longer period will allow deeper understanding of clinical behaviours and patient outcomes to enable ambulance services to identify patterns of clinical behaviour relating to poor practice, adherence to medications management and patient harm that may not be apparent over a short period of time. The CAG were content with this response, noting that although no overall exit strategy is offered, the value of linking the data may persist over years. The CAG therefore are content to provide support for a time period of 5 years, with a duration amendment at that time if an extension of support is required.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to The 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. Support provided for 5 years in the first instance, and a duration amendment will be required at that time to extend ‘s251’ support.

2. Please provide an update at each annual review, regarding the uses of the data at each Trust, to ensure NHS England oversight regarding the data being used at each Ambulance Trust only for the purposes described in the application.

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. See section below titled ‘security assurance requirements’ for further information. **Confirmed:**

   The NHS England **21/22** DSPT review for **NHS Arden & Greater East Midlands Commissioning Support Unit (Arden & GEM CSU)** was confirmed as ‘Standards Met’ on the NHS England DSPT Tracker (checked 16 December 2022)

   Due to the number of Ambulance Trusts involved, it is the responsibility of NHS England, as controller, to ensure that Ambulance 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.

c. 23/CAG/0044 - Optimisation of the FAST MRI protocol: an evaluation of what makes a good breast MRI through detailed analysis of scans from multiple NHS sites contributing to the FAST MRI Programme

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice Chair

Mrs Sarah Palmer-Edwards	CAG Member
Professor Sara Randall	CAG Member
Mr Dan Roulstone	CAG Member
Ms Katy Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from North Bristol NHS Trust set out the purpose of medical research that seeks to define the parameters of scan acquisition that together produce a 'good' quality set of FAST-MRI images.

Despite effective treatments, 30 women die every day from breast cancer in the UK. Early detection of breast cancer saves lives and is the aim of the NHS Breast Screening Programme (NHSBSP), which screens 2.2 million women in England each year. However, mammograms are not good at showing some cancers. Delayed breast cancer diagnosis results in a worse prognosis, a much higher chance of the morbidity associated with metastatic breast cancer and its treatment, and ultimately of mortality. Recent studies have shown FAST-MRI (First post-contrAst SubtracTed Magnetic Resonance Imaging) has potential as a breast cancer screening test. It overcomes the shortcomings of mammography, including poor sensitivity for aggressive cancers. FAST-MRI is much quicker to acquire and interpret (cheaper for the NHS) than the gold standard breast screening modality, full protocol MRI (fpMRI), which is currently reserved to screen only women at high risk of breast cancer. FAST-MRI holds promise to save more lives through breast cancer screening because it can detect aggressive cancers earlier than mammography.

The applicants seek to define the parameters that provide optimal scan quality to produce guidelines for use of FAST-MRI. Clinical staff at participating NHS trusts will identify 10 breast MRI scans which show the types of cancers difficult to detect with mammograms, 5 scans showing grade 3 (aggressive) cancers and 5 showing cancers with lobular histology at diagnosis. These scans will be identified from the local radiology information system and prepared for image transfer. Image transfer SciCom will set up dedicated Cloud storage and a dedicated node on the Image Exchange Portal (IEP) for image transfer. This node will enable automated de-identification of incoming images. To register that an image is being sent, sites will make use of the RSNFT SMART portal to register the case in advance. This portal will include a proforma to be completed by the clinical team that will detail the parameters used to acquire each scan and specific additional information from the scan's report and cancer

histology. The proforma information associated with each study ID will be stored automatically along with the images (using a linked complex salted hash) by SciCom. The applicants do not anticipate that confidential patient information will be accessed by the researchers undertaking analysis but noted that technical issues may occur in the automatic de-identification process. Should this happen, then Royal Surrey County Hospital staff, rather than staff at the patient's site, would have to intervene and may process confidential patient information.

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

Confidential patient information requested

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

Cohort	Patients aged 16 years and over who underwent breast MRI scans at participating hospital trusts from 01 January 2019 onwards.
Data sources	1. Electronic patient records at: a. Royal Surrey NHS Foundation Trust b. University Hospitals Coventry & Warwickshire Gloucestershire Hospitals NHS Foundation Trust c. North Bristol NHS Trust d. Royal Cornwall Hospitals NHS Trust e. University Hospitals Plymouth NHS Trust f. St. George's University Hospitals NHS Foundation Trust g. Great Western Hospital
Identifiers required for linkage purposes	1. NHS Number 2. MRN Number 3. Date of birth 4. Date of death

Identifiers required for analysis purposes	1. Date of birth 2. Date of death

Confidentiality Advisory Group advice

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

1. **Provide further explanation as to why the images and data cannot be pseudonymised to ensure that no confidential patient information is included before leaving the trust.**

The applicants will use the pre-existing Image Exchange Portal to transfer the images, to ensure that all images are de-identified in a consistent manner and to simplify the image transfer process for the busy clinical sites. A dedicated receiving node exists at the Royal Surrey, which will de-identify images automatically upon receipt allowing for the automatic insertion of the matching pseudonym and correct and consistent de-identification.

The CAG noted this information and raised no further queries.

2. **Clarify who will hold the pseudonymisation key and how and when the key will be used.**

The Royal Surrey NHS Foundation Trust will hold the encrypted lookup key. The key will be used to match up the initial client registration and data upload with the images. The key is maintained to allow rectification of any errors up to the point that the images are annotated (confirming they are suitable). Once the image annotation is complete, the key will be disposed of.

The CAG noted this information and raised no further queries.

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

a. **It must be explained clearly that confidential patient information may be disclosed outside the direct care team.**

b. **It must be explained that support under s251 is in place.**

The applicants provided a revised poster. The CAG noted this information and raised no further queries.

4. **Further patient and public involvement needs to be undertaken with the representative group to discuss the potential disclosure of confidential patient information. Feedback from the discussion is to be provided to the CAG.**

The applicants undertook further consultation with their Patient and Public Involvement group. None of the respondents said that they would have an issue with their scans being reviewed by clinicians outside their care team, as they would not be able to be identified on this review.

Members stated that they specifically would be wary of contacting individuals in this cohort due to the high likelihood that the woman had or was going through invasive treatment.

All members agreed that if the correct procedure to acquire the scans had been taken and relevant approvals and permission received, along with all reasonable steps to anonymise scans, they supported the study.

The CAG noted this information and raised no further queries.

5. **Provide justification on why it is necessary to use patients' full names for linkage.**

The applicants clarified that they did not require the names of the patients and will not collect this data.

The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research

Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 2 May 2023.**

2. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

   Due to the number of participating organisations involved it is the responsibility of **North Bristol NHS Trust** as controller, to ensure that participating Trusts/Organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

d. 23/CAG/0055 - Understanding patient uptake and experience of interpreter services in primary care

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Mr David Evans	CAG Member
Mr Anthony Kane	CAG Member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Queen Mary University of London set out the purpose of medical research that seeks to investigate how interpreting services are currently implemented in primary care.

In the UK there is a growing and ageing population of people for whom English is not their first language. Interpreter services are provided to ensure patients, carers and clinicians understand each other, and to try to avoid worsening inequalities in healthcare access and outcomes. This is particularly important in primary care because it is the main source of NHS healthcare. Over 98% of people in the UK are registered with a GP, so provision of good interpreter services in primary care is key to the reduction of health inequalities. Research suggests that providing interpreters improves quality of care, and when patients with limited language proficiency have access to trained professional interpreters, they report higher patient satisfaction, higher comprehension and there are fewer errors of potential clinical consequence and equalisation of healthcare access. Findings will help understanding of the potential impacts of interpreting services on reducing health inequalities in primary healthcare access.

A researcher is undertaking a number of different methodologies at 4 participating General Practitioner (GP) surgeries, including consented staff interviews and consented interviews with commissioners and policy-makers at local and national levels, documentation reviews, and verbally consented observations of patient consultations. These elements do not require ‘s251’ support.

However the researcher, who is not considered direct care team, is also undertaking ethnographic observations, of clinical meetings of different types e.g. primary care staff meetings, commissioning meetings. Support under Regulation 5 is required 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.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application

form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients who were discussed during clinical observations at participating GP practices
Data sources	Clinical meetings/observations in participating GP practices, recorded via written field notes, at the following sites; 1. Page Hall Medical Centre, 101 Owler Lane, Sheffield, S4 8G 2. Evergreen Surgery, 1 Smythe Close, Edmonton, N9 0TW 3. Mathukia Surgery, 281 Ilford Ln, Ilford, IG1 2SF 4. Jubilee Street Practice, 368-374 Commercial Road, Tower Hamlets, E1 0LS 5. St Andrews Health Centre, 2 Hannaford Walk, Bow, E3 3FF 6. Bromley by Bow Health Centre, St Leonards Street, London, E3 3BT
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.

1. Please alter the poster to make it clear that the researcher is not part of the direct care team, that the information overheard would be identifiable information, and the fact that the applicant has a legal basis to do this under 'Section 251'. Alternatively, please alter the poster to lead on to either a leaflet or a website, which contains this additional information, and provide to CAG for review.

The applicant provided an updated poster as per CAG advice. The Sub-Committee were content with this response.

2. Further patient and public involvement needs to be carried out directly with a small group of patients requiring interpreter services, to include discussion of the use of confidential patient information as proposed in the application, and feedback provided.

The applicant undertook a group discussion with 7 Bangladeshi women, who had experience of using interpreter services, and discussed the use of confidential patient information as per advice from CAG. Feedback from the discussion has been provided. The Sub-Committee were content with this response.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 29 March 2023**

2. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   Due to the number of participating organisations involved it is the responsibility of **Queen Mary University of London** as controller, to ensure that participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

e. 23/CAG/0007 - A UK-wide study of paediatric-onset chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) epidemiology, clinical presentation and outcomes

Name	**Capacity**
Dr Martin Andrew	CAG member
Professor William Bernal	CAG alternate vice-chair
Dr Pauline Lyseight-Jones	CAG member
Ms Diana Robbins	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from University College London Hospitals NHS Foundation Trust set out the purpose of medical research that seeks to determine the epidemiology, clinical presentation, natural history, and outcomes of individuals with paediatric-onset chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) in the UK.

CIDP is a chronic, treatable, immune-mediated inflammatory disorder of the peripheral nervous system, often with a mixture of motor and sensory impairment. Onset is usually in adulthood, but childhood (paediatric)-onset cases are recognised. As CIDP is rare, little is known about its natural history and the epidemiology of paediatric-onset CIDP in the UK is unknown.

The National Immunoglobulin Database holds the records of all patients undergoing immunoglobulin treatment, which is a very common, first-line treatment for CIDP, in England, Scotland and Northern Ireland. The applicants seek to obtain confidential patient information from this database and to disclose this information to local clinicians to be cross-referenced with patient records.

A Redcap database (Data Safe Haven version) will be set up. Confidential patient information will be disclosed from the National Immunoglobulin Database to the Redcap database held at University College London. Confidential patient information will then be disclosed to the NHS trusts which treated each patient. If patients are under ongoing follow-up by local clinicians, local clinicians will attempt to obtain informed consent for prospective data collection. If individuals have moved to different areas or have been discharged from treating services, then patients will not be contacted directly to obtain consent for retrospective analysis of their previous medical records. Clinicians who have patients with paediatric-onset CIDP will also report patients to the study group. This identifiable information will be used to identify patients to approach for consent.

A recommendation for class 2, 3, 4, 5 and 6 support were requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Patients of any current age diagnosed at any point in life with confirmed or probable CIDP by an adult or paediatric neurologist, whose onset of symptoms was at or under 18 years of age.

Data sources	1. National Immunoglobulin Database, held by MDSAS on behalf of NHS England 2. Data from the hospital trusts that provided treatment
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number 4. Date of birth 5. Date of death 6. Postcode – district level 7. Sex
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. Date of death 4. Postcode – district level 5. Gender 6. Ethnicity 7. Treating hospital/NHS trust

Confidentiality Advisory Group advice

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

1. **Due to the rarity of the condition and potential small participation numbers involved, please provide clarification on how the increased risk of identification would be managed.**

The applicants acknowledged that the rarity of the condition increased the risk of identification if too much identifiable information is made available publicly. Because

of this, any publications will not just avoid personally identifiable information such as name and age, data will also be presented on the larger cohort (e.g. median age of the cohort, proportion of female/male patients). If there are any publications that present on individual potentially identifiable patient information, further consent would be sought for this, in accordance with journal guidelines.

The CAG agreed that the information about further consent was unclear as it appeared to relate to publication in journals and also suggested that consent might be possible in specific cases, should the applicants wish to report on them. Members agreed that this was not an issue that prevents the CAG from recommending support, but noted that the applicants should remain cautious over the risk of re-identification from use of small numbers.

2. **Patient and public involvements need to be undertaken. This needs to:**

    a. **Include patients with CPID and/or their relatives, or patients and/or relatives of those with similar conditions,**

    b. **Include discussion on how patient notification can be undertaken and how a dissent process can be implemented.**

The applicants had approached a small focus group of patients with CIDP to discuss the research proposal and relevant documents. They have reviewed the documents and agreed with the suggested documentation, as well as the applicants' suggestions for the patient notification and dissent processes.

The CAG noted the information provided. Members agreed that patient and public involvement would need to be carried out as the project progresses. Feedback from the further activity carried out needed to be provided at the first annual review.

3. **Provide clarification on the exit strategy for patients included under s251 support and the consent process for patients on active follow-up.**

The applicants explained that the information collected with allow the identification of patients treating clinicians, who will report back on the initial presentation and management. For patients under active follow-up, the treating clinicians will consent patients. The applicants expect that consent will be sought within 12 months of the site set-up for most patients. Consent will be the exit strategy for these patients.

The applicants recognised that an unknown proportion of patients identified will no longer be under ongoing follow-up, because of disease remission. In cases that have been discharged from ongoing care, the applicants expect that it would not be possible to approach these patients to formally consent them for ongoing data collection. However, it is important that the applicants know how many patients fall within this category and whether there are any identifiable clinical differences between these patients and patients undergoing ongoing treatment. Because of this, the applicants will still request for site PIs to report back on clinical information where this is still available. The applicants note that confidential patient information will need to be retained to allow for this further information to be collected.

At the end of 5 years after formal study commencement, it is unlikely that the applicants will be able to obtain further information on patients who are not already available for consent. As such, at the end of this 5-year period, all remaining information from non-consented patients will be pseudonymised, removing the patient's name and date of birth from the database. All other clinical information that is available will be retained until the end of the full study period.

The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Feedback from the further activity carried out needed to be provided at the first annual review.

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

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

   Confirmed:

   The NHS Digital **21/22** DSPT reviews DSPT for **University College London, University College London Hospitals NHS Foundation Trust** and **MDSAS** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 22 June 2023).

f. 23/CAG/0056 - How to improve communication from GPs to hospital specialists at the point of referrals?

Name	**Capacity**
Dr Tony Calland MBE	CAG Chair
Mr Andrew Melville	CAG Member
Ms Rose Payne	CAG Member
Ms Katy Cassidy	CAG Confidentiality Advisor

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research that seeks to examine the impact of use of a primary-secondary care interface on communication and relationships between GPs and hospital specialists.

A recent study by the James Lind Alliance Priority-Setting Partnership in the UK identified communication issues between primary and secondary care systems as the third most important unanswered research question in improving patient safety. Most research exploring the communication processes across primary-secondary care interface has concentrated on discharge processes from hospital care to community care, rather than the reverse, i.e., the initial GP referrals from primary care to specialists.

The applicants will undertake a qualitative study to evaluate the Granta model of integrated care between GPs and hospital consultants. Interviews will be held with GPs from the Granta Primary Care Network (PCN), and a neurologist from Cambridge University Hospitals and a psychiatrist from Cambridge and Peterborough NHS Foundation Trust who frequently work with this GP group. Interviews will also be held with other stakeholders within the Trusts and PCN. Focus groups will also be held with Granta staff and teleconference meetings between the Consultant Neurologist or Psychiatrist and the Granta GPs will be observed.

The applicants sought support under the Regulations due to the possibility that confidential patient information may be disclosed during the observations of meetings. The researcher will take notes about the interactions occurring in the teleconference, but will not record any patient identifiable information, and no audio or video recordings will take place.

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

Confidential patient information requested

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

Cohort	The cohort included in the study are members of staff. However, incidental disclosures of confidential patient

	information may be made when observations of staff meetings take place.
Data sources	1. Incidental disclosures of confidential patient information may be made during observations of staff meetings at: a. The Granta Primary Care Network (PCN) b. Cambridge University Hospitals NHS Foundation Trust c. Cambridge and Peterborough NHS Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information are required for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information are required for analysis purposes
Cohort	The cohort included in the study are members of staff. However, incidental disclosures of confidential patient information may be made when observations of staff meetings take place.

Confidentiality Advisory Group advice

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

1. **The poster needs to be updated to clearly describe the purpose of the study and the role of CAG.**

The applicants provided an updated poster. This was reviewed by the CAG.

Members were largely satisfied but asked that the explanation of the CAG and s251 was revised. The CAG suggested that the wording, "the Health Research Authority,

following advice from the Confidentiality Advisory Group, agreed that s251 support should be given for the application activity" was used. The amended poster needed to be provided for review.

2. **If possible, please display the poster on the practice's website.**

The applicants advised that the lead GP at Grant Medical Practices would be asked if the poster could be displayed on the practice website. The CAG noted this and raised no further queries.

3. **A telephone contact number and address need to be included within the poster, as a means of opt-out.**

A telephone number was included on the revised poster. The CAG noted this and raised no further queries.

4. **Clarify when the applicant will delete the list of dissenters regarding the opt-out process.**

The list of dissenters will be kept by the research team until the end of the teleconference observations, which will be a max duration of 6 months from the start of the study. The CAG noted this and raised no further queries.

5. **Clarify whether the incidental disclosure of confidential patient information was specifically discussed within the patient and public involvement group. If not, please raise this within the next meeting, and provide feedback to CAG.**

The issue of incidental disclosure of patient identifiable information without consent during teleconference observations was discussed with PPG committee members. They were happy with the research study as proposed. The CAG noted this and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support

1. The wording on the poster describing the CAG role needs to be revised to the following, “The Health Research Authority, following advice from the Confidentiality Advisory Group, agreed that s251 support should be given for the application activity” was used. The amended poster needed to be provided for review.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 05 June 2023.**

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

   The NHS England **21/22** DSPT reviews for **Granta Medical Practices**, **Cambridge University Hospitals NHS Foundation Trust** & **Cambridge and Peterborough NHS Foundation Trust** were confirmed as ‘Standards Met’ on the NHS England DSPT Tracker (checked 27 June 2023).

g. 23/CAG/0052 - The health effects of police diversion for drug-involved suspects

Name	Capacity
Dr Joanne Bailey	CAG Member

Dr Rachel L Knowles	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Umar Sabat	CAG Member
Ms Clare Sanderson	CAG Alternative Vice Chair
Ms Emma Marshall	HRA Confidentiality Specialist
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from The University of Kent (with both The University of Kent and the Department for Health and Social Care confirmed to be joint data controllers), set out the purpose of medical research that seeks to study the effect of 'police diversion' on people who have some involvement in use of controlled drugs. 'Police diversion' happens when someone is in contact with the police, for example because they have been found in possession of controlled drugs, and is offered an alternative solution instead of traditional punishments such as a caution or charge. The alternative solution might include educational programmes, one-to-one support, and referral to structured treatment for drug dependence. These schemes exist in some police forces and not others. Currently, the benefits of police diversion are not well understood.

Many police officers and government policy-makers recognise that people involved in drugs have poor health and social outcomes. Traditional punishments used by the police can worsen these outcomes by affecting employment prospects, social relationships, and mental health. 'Diversion' to educational or treatment programmes may have substantial benefits both for the individual involved in drugs and for society. However, there is very little robust research into these benefits, which means that diversion schemes do not attract long-term sustainable funding. The study aims to estimate the effect of police diversion schemes on reoffending rates and the health and wellbeing outcomes of people who use illicit drugs. This is a population with poor health outcomes and high health and social care costs. The frequent contact with the police means that police diversion is an opportunity to provide health interventions to a vulnerable and under-served group. This supports the NHS Long Term Plan and the Prevention Programme. The results are intended to inform policies that improve health outcomes and reduce health and social care costs for this group. Local partnerships of

police and healthcare organisations (such as drug and alcohol treatment services) will use the results to design pathways that reduce criminalisation, stigmatisation, and harm from controlled drugs. The descriptive data will also help the NHS understand the health needs of this population, which are not well-known because illicit drug use is not well-recorded in routine data.

Participating police forces will identify individuals who are suspected of offenses related to drugs, meeting the eligibility criteria. Data disclosed from police force to the Office for Health Improvement and Disparities (OHID) part of the Department for health and Social Care (DHSC) is not in scope for 's251' support. The police force will disclose identifying information such as PNC ID if available; name, sex, gender, date of birth, and postcode, (which does not meet the criteria for confidential patient information as it is not in association with a health record), alongside ethnicity if available, and baseline police data. Name, sex, gender, date of birth and postcode will be disclosed to NHS England, for the purposes of linkage to the personal demographics service (PDS), in order to provide the applicants with NHS number. This linkage requires 's251' support, as this constitutes confidential patient information. Identifiers are linked by OHID (DHSC) to the NDTMS dataset, alongside the police information and MoJ (PNC) data, to create a pseudonymised dataset for analysis, none of which requires 's251' support as the ministry of Justice data is not confidential patient information, and the NDTMS cohort are consented. Linkage with PNC and NDTMS will be undertaken at 2 separate timepoints. NHS number is then used to link within DHSC to Hospital Episode Statistics and ONS mortality data, which also requires 's251' support as this constitutes confidential patient information. Applicants will create a pseudonymous dataset for analysis.

The main analysis will be based on comparing individuals in areas with diversion schemes to those in areas without these schemes. The two primary outcomes are; hospital episodes related to drugs, alcohol, or accidents, and reoffending, defined as any proven offense in the 12 months after the index police contact. Secondary outcomes will be entry into structured treatment for drug or alcohol use in a community setting; and among those who start drug or alcohol treatment, retention in treatment for at least 28 days.

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	Individuals will be eligible to participate if they were in contact with the police in relation to drugs between October 2021 and September 2022. Applicants estimate the cohort will be between 3,600 and 8,400 individuals. Participating police forces will identify individuals meeting the following criteria: (1) Had police contact between 1 October 2021 and 30 September 2022 (inclusive) (2) Contact was in relation to a qualifying offence committed in the police force area (listed in application) (3) Lived in the police force area at date of police contact (4) Was aged 18+ years at date of police contact
Data sources	1. NHS England – Patient Demographic Service 2. OHID (DHSC): a) Hospital Episode Statistics (HES) b) Office for National Statistics (ONS) mortality data Out of scope for 's251': • Police force data • MoJ – PNC data • OHID (DHSC) – NDTMS

Identifiers required for linkage purposes	Linkage to PDS: 1. Name 2. Sex 3. gender 4. Date of Birth 5. Postcode Linkage to HES/ONS: 1. NHS number
Identifiers required for analysis purposes	Pseudonymous for analysis; • Month and year of death (derived full date of death) • Ethnicity • Age • Multiple Deprivation score (derived from postcode)

Confidentiality Advisory Group advice

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

1) **Please confirm whether the application has a lawful basis for the sharing of police data with OHID.**

The applicants confirm they have discussed this with data protection officers at DHSC, University of Kent, the Ministry of Justice (for police data on the Police National Computer) and the National Police Chiefs' Council and participating police forces (for police data held by individual forces). The data processing will be done under the UK GDPR legal basis of 'public task'. The project may involve processing of 'special category' (sensitive) information, which is permitted under article 9(2)(j) of UK GDPR and 'criminal offence data' as defined under article 10 of UK GDPR. The CAG were content with this response.

2) **Please confirm whether the DHSC would be joint data controllers with the University of Kent for this CAG application.**

The applicant has confirmed that DHSC and University of Kent will be joint data controllers for the application. This has been confirmed by University of Kent (Kate Kremers, Assistant Director, Assurance, and Acting Data Protection Officer) and DHSC (Adam Grindrod, Data Protection Officer). The CAG were content with this response.

3) **Please confirm at all points of the data flow whether it is sex, gender or both required for the linkage.**

The applicant confirmed they will request both sex and gender from police forces. Discussions with police forces suggest that definitions of 'sex' and 'gender' are not always consistent across organisations, and applicants will therefore also record the definition used by each police force for these variables. The data in the analytical dataset is likely to be the "lowest common denominator" across these variables, which may be sex (male/female/other or unknown). Applicants have updated the data flow diagram to clarify that both sex and gender will be requested from police forces, and have provided v1.2 of the data flow diagram. The CAG wee content with this response.

4) **Please update the patient notification materials as follows, and provide to CAG for review.**

    a. **The poster doesn't explain what police diversion schemes are – this should be included, as the control group may not know.**

    b. **The legal basis for processing of 's251' and that the application has been supported by the Health Research Authority (HRA), following advice from the Confidentiality Advisory Group (CAG), should be included on the poster.**

    c. **There is an email only for opt-out, a postal address and phone number should also be included.**

d. **The language regarding ‘requesting’ an opt-out is not correct terminology, as it suggests patients can ask and it might not be given. Please re-word this.**

e. **CAG feel a layered approach should be undertaken, for example a QR code on the poster that links on to a longer privacy notice on a website if people want to have further information.**

The applicant updated the document as per CAG advice, and CAG were content with the notification provided.

5) **Please confirm if it is possible for the police force to operate the study specific opt-out, and provide a period of 6 weeks for participants to opt-out once the notifications have been displayed.**

The applicant has confirmed that this is possible, and have updated the notice giving participants an opportunity to opt-out by contacting the participating police force, and provided 6 weeks to opt out. The dates assume that the notice is published on 1 August 2023; and applicants will update these dates depending on when the notice is posted by each force. After 6 weeks, participants can still opt out before November 2024 by contacting DHSC. The CAG were content with this response.

6) **Please identify the drug recovery organisations who may be able to help publicise the research by displaying the posters.**

The applicants are currently aware of the following drug recovery organisations that are working in partnership with police forces:

- Durham – Humankind and Addaction
- Thames Valley – DrugLink, One Recovery, and RedSnapper
- West Midlands – Cranstoun
- Humberside – Change Grow Live
- Hampshire – Inclusion Recovery Hampshire and 24/7 Hampshire
- Greater Manchester – Change Grow Live and Achieve

Police forces work in partnership with drug recovery organisations and have specific officers who lead on drug-related issues. Applicants will ask these officers to identify local organisations and ask them to publicise the research. The CAG were content with this response.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 27 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. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS England 21/22 DSPT reviews for **OHID (DHSC)** and **NHS England were** confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 17 April 2023).

h. 23/CAG/0046 - Thames Valley and Surrey (TVS) sub national secure data environment (SNSDE) programme

Name	Capacity
Dr Joanne Bailey	CAG Expert Member
Dr Patrick Coyle	CAG Vice Chair
Dr Pauline Lyseight-jones	CAG Lay Member
Professor Sara Randall	CAG Lay Member
Dr Murat Soncul	CAG Alternate Vice Chair

Ms Emma Marshall	Confidentiality Specialist

Context

Purpose of application

This application from Oxford University Hospitals NHS Foundation Trust sets out the purpose of medical research.

The Thames Valley and Surrey (TVS) area represents approximately 4.3 million people. This application proposes to collect all primary and secondary care patient data into a Sub-National Secure Data Environment (SNSDE) for the purposes of conducting medical research. A data access committee will review and approve applications to access extracts from the database, with a particular interest in research proposals from within the Thames Valley and Surrey region. Upon approval, researchers will be provided with secure access to the data to undertake analysis, without the data leaving the NHS. The SNSDE will be used to conduct translational research to improve delivery or patient care across a broad spectrum of disease and clinical areas.

Support is requested for the flows of confidential patient information from participating organisations to Oxford University Hospitals NHS Foundation Trust to create the SNSDE. Confidential Patient Information will flow from GP practices (via system suppliers such as EMIS/TPP) and NHS Trusts (including mental health and ambulance Trusts). Specialist data (e.g. radiology data) may flow direct from a processor (e.g. Insignia) rather than the Trust extracting the data themselves. A core set of data will flow at time intervals agreed with each processor, with additional specialist extracts required for specific research projects. Data will retrospectively be collected from the time that a full electronic patient record is available and prospectively, and shared care records will not be used to collate data.

Patient data will be checked, linked, de-identified, filtered, and transformed in the data processing environment, to produce a research database that can be used to produce extracts for research purposes. This will be held within the data processing environment and not made available to researchers. It can be accessed only by the data management team for the TVS SNSDE, all of whom are employed by or contracted to the coordinating organisation, Oxford University Hospitals NHS Foundation Trust. Extracts from the database – produced for specific, approved

research programmes – will be prepared within the data processing environment and subjected to additional checks before being securely copied across the area that researchers will access.

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

Confidential patient information requested

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

Cohort	All patients receiving NHS treatment within the Thames Valley and Surrey (TVS) area
Data sources	Electronic patient records held at: 1. Buckinghamshire, Oxfordshire, and Berkshire West (BOB ICS)* 2. Oxford University Hospitals NHS Foundation Trust 3. Oxford Health NHS Foundation Trust 4. Berkshire Healthcare NHS Foundation Trust 5. Royal Berkshire NHS Foundation Trust 6. Buckinghamshire Healthcare NHS Trust 7. South Central Ambulance Service NHS Foundation Trust 8. Frimley Health and Care (ICS)* 9. Frimley Health NHS Foundation Trust 10. Surrey Heartlands Health and Care Partnership (ICS)* 11. Ashford and St. Peter's NHS Foundation Trust

	12. Royal Surrey County Hospital NHS Foundation Trust 13. Surrey and Sussex Healthcare NHS Trust 14. Surrey and Borders NHS Foundation Trust 15. South East Coast Ambulance Service NHS Foundation Trust 16. Epsom and St Helier University Hospitals NHS Trust 17. CSH Surrey (Central Surrey Health) 18. First Community Health and Care 19. Great Western Hospitals NHS Foundation Trust 20. Milton Keynes University Hospital NHS Foundation Trust *this includes a total of 343 GP practices within the TVS
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. GP registration 5. Date of birth 6. Date of death 7. Postcode – unit level
Identifiers held in the data processing environment	1. Initials 2. Full name 3. Address

	4. NHS number 5. Hospital ID number 6. GP registration 7. Date of birth 8. Year of birth 9. Date of death 10. Postcode – unit level
Identifiers available to researchers	1. Postcode – sector level 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.

1. Request for further information 1

The members previously commended the patient and public work to date and reiterated this in considering the response. They also thought that the visual representation of the public involvement workshops was a creative way to convey the outputs, but also felt that this output did not enable CAG to have a clear response to the question posed. CAG asked to "*Provide more information on the outputs from patient and public involvement and engagement activities to date, particularly around any negative feedback or concerns raised, and feedback from privacy advocacy groups*".

a. Please provide further written information on whether there any negative feedback was received, whether concerns were raised, and whether any modifications have been made as a result.

b. Members noted one concern raised was individuals not being informed if any findings of significance were identified, which CAG

understands is the current position. Please may you provide specific further information on this discussion within the workshop, were participants more accepting of the rationale following the discussion, and any modifications made as a result?

Applicant response

a. Our workshops so far have been interactive sessions, exploring with participants their views on a range of subjects to help inform drafting of the policy and procedures for the SDE, which is ongoing. The group will be consulted during this process to ensure we have taken into account views wherever possible.

Overall feedback emphasised the need for a diverse range of views to be heard – hence the seldom heard work that is being completed over the coming months.

The questions asked at the workshops included:

1: What data should be included in the SDE?

Areas of concern raised with respect to this question included:

- Data potentially being poor and/or incomplete and therefore findings being skewed or systematically biased
- Information shared being identifiable eg faces being seen
- Sensitivity of specific types of information eg
    - Genomic information
    - Sexually transmitted infections
    - Mental illness
    - Religious and political beliefs
    - Trans status
    - Domestic violence

The issues raised are not new and need to be addressed in the public awareness work being planned, which includes supporting people to understand what data may be used for and the opt-outs they can apply.

2: What should the data be used for?

The key issue here was in relation to having a transparent process – who/what/why - for project approval that includes patients and the public. Concerns raised that some organisations may not have 'benefit to the NHS/patients' as their motivation. Public benefit was the key criteria that should be included in the data access process being developed. What constitutes public benefit will be further explored in a workshop being planned currently. It was also clear that the use of the term commercial v non-commercial research was not seen to be helpful. We are now referring to the development of our value, rather than commercialisation, strategy.

b. Specific discussion on the issue of individuals being informed of any findings of significance has not taken place. This will be discussed at future workshops and sessions with patients and the public, and we will modify the ways this is explained to make sure the rationale is understood.

Per our CAG response 10 May, the current position is for issues of data quality and consistency to be flagged to participating NHS organisations. Findings will not be communicated regarding individual patients and patients will not be re-identified as part of this process.

In the unlikely scenario that a finding is identified that a researcher feels would be of significant and immediate benefit to the patient in question, this would be flagged with the Caldicott Guardians acting on behalf of both the SNSDE and the contributing NHS organisation.

2. Request for further information 2

Thank you for providing further information on the planned workshops over summer 2023 with a number of groups. Members noted that further specific involvement was planned with Milton Keynes University Hospital NHS Foundation Trust and Great Western Hospitals NHS Foundation Trust, with dates of 14 and 15 June referenced. It was however unclear whether these were the public involvement sessions, or precursor meetings to gain participation.

a. **If these were the public involvement sessions is there any early feedback about the acceptability of use of confidential patient information without consent to set up the SDE?**

Applicant response

These were precursor meetings, not public involvement sessions – with the aim of broadening awareness of our patient and public activity and widening participation in

our community of practice. Off the back of these meetings, we expect additional lay members and PPIE professionals to be added to the community of practice.

N.B Meetings were held with Milton Keynes University Hospital NHS Foundation Trust and Great Western Hospitals NHS Foundation Trust at individual trust level because they are working independently of their ICBs for this programme. This is in contrast with our approach across the three ICBs participating in the TVS SNSDE (BOB, Frimley, Surrey Heartlands), where we work through the ICBs rather than the NHS trusts they represent individually on equivalent meetings over the coming weeks.

3. Request for further information 3

Please can you confirm that the patient notification materials provided will be used in Milton Keynes University Hospital NHS Foundation Trust and Great Western Hospitals NHS Foundation Trust and across all areas of these trusts, not just in the cancer depts? That is to ensure patients at these trusts reasonably expect that their data will be included within TVS SDE.

Applicant response

Patient notification materials will be used across all areas of all NHS trusts participating in the TVS SNSDE, including Milton Keynes University Hospital NHS Foundation Trust and Great Western Hospitals NHS Foundation Trust. All NHS trusts will be expected to display materials and update their privacy notices accordingly in a disease-agnostic way.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support

1. Support is for research purposes only

2. Support is provided for 5 years from the date of this letter.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 14 June 2023**

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 Digital 21/22 DSPT reviews for **Oxford University Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 17 April 2023)

2. New Amendments

21/CAG/0094 – Time limited access for NHS Digital to undertake record linkage of East Anglian Air Ambulance patients to HES and ECDS

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from East Anglian Air Ambulance (EAAA) aims to link routinely collected clinical data regarding patients treated by East Anglian Air Ambulance to HES data to audit and evaluate the care provided by the air ambulance in relation to the complete patient pathway and patient outcomes. This application has support to link information regarding the cohort of patients from calendar year of 2020.

This amendment sought support to change the cohort year from 2020 to the 1st April 2021 to 31 March 2022. The reason for the requested change in date of the cohort is due to the time taken for the application to NHS England to be processed, meaning that 2020 is now too long ago. Also, NHS England data is available on a

per financial year basis and so requesting a calendar year would mean additional cost to straddle the financial years, which would be a poor use of charitable (public donated) funds. Changing to a cohort date of 2021-22 means the data is more up-to-date and therefore more useful for the intended service evaluation/audit purposes. Furthermore, due to improvements in data quality over time, in particular around better recording of NHS numbers, this more recent time period is likely to link better and have better data quality overall. Therefore, the linkage will be more accurate and valuable.

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 21/22 DSPT reviews for **NHS Digital and East Anglian Air Ambulance** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 24 May 2023)

21/CAG/0085 – The Child Health Clinical Outcome Review Programme (CH-CORP)

Name	Capacity

Dr Murat Soncul	CAG Alternate Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has 's251' support for a core methodology of data collection for The Child Health Clinical Outcome Review Programme (CH-CORP). Confidential patient information regarding all eligible cases is disclosed from participating healthcare providers to the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), a sample is selected, and confidential patient information is used to follow-up with clinicians involved in the patients care by way of questionnaire (completed online in pseudonymised format), and relevant copies of

extracts from the patient's case notes are also disclosed from treating clinicians to NCEPOD.

HQIP commission one topic each year. This year the topic is Juvenile Idiopathic Arthritis. The standard methodologies for retrospective case identification, sending of questionnaires to clinicians and anonymous case note review will be followed.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chairs' action. The Alternate Vice-Chair was content to support this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   Confirmed: The NHS England 21/22 DSPT review for National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 25 May 2023).

19/CAG/0139 – The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3)

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

Context

Amendment request

This application from the University of Nottingham aims to evaluate two testing approaches to identify Group B Streptococcus in pregnant women.

The applicants have existing support to process data from; electronic health records from participating maternity units in England and Wales, the National Neonatal Research Database, Patient Episodes Dataset Wales held by the DHCW (previously NHS Wales Informatics Service), Group Strep B Infant Sepsis reports held by Public Health England, Group Strep B Infant Sepsis reports held by Health Protection Wales, and the English Maternity Services Dataset and HES data held by NHS Digital, the Paediatric Intensive Care Audit Network (PICANet) and Badgernet (Maternity and Neonatal). Data from these sources will be processed in order to create a dataset for analysis. Data is retained by the Health Informatics Centre at the University of Dundee.

‘s251’ support was initially in place for NHS England (formerly NHS Digital) to provide data restricted to the participating GBS3 hospital/ trust systems during a specific time period, directly to the Health Informatics Centre at the University of Dundee, and would include the NHS number, Date of Birth (DOB) & Postcode of the trial participants to enable linkage with other datasets from other databases. After lengthy consideration by NHS England, it has been concluded that the trial cohort cannot be extracted by NHS England from MSDS as previously specified. The trial cohort includes all women who gave birth or intended to give birth at a GBS3 participating site during the data collection window for each site. This complex query was beyond the data structure, and capability and capacity of the NHS England at this time.

The alternative proposal from NHS England is for GBS3 to request the total maternity cohort (including births at non-GBS3 sites) for the financial years covering the GBS3 data collection period (20-24). This would include identifiers such as maternal NHS, DoB and postcode, booking and actual place of delivery, date of delivery. The GBS3 data manager would perform the filtering themselves, within the TRE at the Health Informatics Centre at the University of Dundee, to extract the trial cohort.

Applicants will first identify maternity care records whether the intended/ booked place of birth does match the actual place of birth at a Trust level. The majority of the records will fall into this category and will automatically be added to trial cohort. Applicants will then identify discrepant records, which will be grouped into booked care at a GBS3 participating Trust or not booked at a GBS3 site. Those booked at GBS3 participating sites will be added to the trial cohort. Those not booked at a GBS participating sites will be identified as the non-GBS3 cohort. The trial cohort will then be further limited by the time windows for each site’s participation, for the 9-22 month “data collection” interval. The NHS numbers of the trial cohort would then be returned to NHS-E and used to extract the remaining required data fields from the HES and mortality datasets. This amendment is for the GBS3 trial to receive the total maternity cohort. The process for Welsh maternity data from NHS Wales Informatics Service (NWIS) has not changed.

This amendment sought support for the GBS3 trial to receive the total maternity cohort from NHS England, regarding the financial years 20-24, taken from the Maternity Service Data Set (MSDS) and disclosed to the Health Informatics Centre at the University of Dundee. The amendment is required to enable the GBS3 trial to obtain the data required to answer the research question. The GBS trial is midway through the “recruitment” phase with women being offered testing for GBS at 35 maternity units throughout England and Wales. This flow is the option proposed by NHS England to

overcome the limitations of their capacity and capability to perform the extractions, and unfortunately this means applicants will receive more data than they require.

Applicants are not able to inform data subjects in non-GBS3 sites of the intention to obtain their data, and use it in a very limited way, as applicants do not have local approval to display posters or provide leaflets at non-GBS sites. To do so would cause confusion amongst maternity service users, as it would refer to a study that they could not participate in in the usual manner. The applicant has undertaken patient and public involvement on this point with Group B Strep Support, who consider that it would be inappropriate to try to inform maternity service users at non-participating sites in England and Wales.

The applicants have also informed CAG that they are no longer seeking data from data providers holding data on Scottish NHS patients. These were listed as Public Health Scotland and NRS. The trial team was unable to engage with any NHS Boards in Scotland due to logistical and financial barriers. This is however out of scope for this application, as it is with regards to Scottish data, and does not alter the 's251' support.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Chair was supportive of the amendment, noting that this was out of the applicants control.

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 **21/22** DSPT review for **the University of Nottingham and the DSPT equivalent for NHS Digital** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 30 May 2023)

Due to the number of organisations involved it is the responsibility of University of Nottingham, as controller, to ensure that all organisations processing confidential patient information without consent 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. These will not be individually checked by CAT as there are more than 5 organisations.

Health Informatics Centre at the University of Dundee – HSC-PBPP approval confirmed 04 November 2021

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

21/CAG/0173 – Establishing the burden of vaccine preventable acute lower respiratory tract infections in primary care, UK: Avon-CAP GP2

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

Context

Amendment request

This application aims to describe the incidence of acute lower-respiratory tract infection (aLRTI) in adults who present to primary care, and to estimate the proportion caused by vaccine preventable infections, including Streptococcus pneumoniae, Respiratory Syncytial Virus (RSV) and SARS-CoV-2. 's251' support is currently in place to allow disclosure of confidential patient information from participating GP practices to the University of Bristol, for those eligible patients that cannot be approached for consent,

and also to allow research nurses/practitioners, who are not considered to be part of the direct care team, to access confidential patient information in patient records, and out of hours discharge letters from Brisdoc at participating GP practices, to screen patients for eligibility and approach patients for consent, into both the surveillance study and the sampling study.

Applicants already have ethical approval to collect a small, anonymised descriptive data set on patients who decline consent.

This amendment informed CAG that the study would be including patients that had registered a National Data Opt Out into an equivalent anonymised descriptive dataset collected by the direct care team. This change does not require 's251' support, as there is no change to any 's251' supported flow. Applicants are reducing the amount of information given to them as part of this anonymous dataset. This is therefore accepted by CAG as notification only.

This amendment sought 's251' support for the inclusion into the anonymised descriptive dataset, a set of data regarding individuals who don't speak English (and therefore are not eligible for the study so wouldn't be included in surveillance arm). 's251' support is required because this processing would be undertaken by researcher, rather than direct care team.

With regards to the surveillance arm, 's251' support is already in place for those eligible patients that cannot be approached for consent (i.e. those who die or who applicants are unable to contact despite concerted efforts). To note – these are not non-responders, as they will never have received a contact from the research team who have been trying to contact them by phone only. However at the time of support, this did not specifically include some common subgroups that the applicants have now found. These subgroups are listed in the amendment, and appear to be eligible patients that cannot be approached for consent, therefore this amendment is submitted for clarity to ensure that these groups are included officially in the support provided.

The amendment therefore sought 's251' support to clarify that the following sub-groups of eligible patients who cannot be approached for consent, can be included in the surveillance arm;

- Patients whom the GP has advised that it is not appropriate for the research team to contact (e.g. due to a recent bereavement of a close family member OR as the patient is very frail and the GP feels it is not appropriate to make contact etc.)
- Patients who have been identified as eligible but subsequently move GP practice, prior to a successful contact being made with them.
- Patients who are dying
- Patients who lack capacity where it is not possible to identify someone willing to act as a consultee (either personal or nominated)
- Patients who lack capacity where there have been three failed phone contacts with a potential personal consultee and three failed phone contacts with a potential nominated consultee

The applicant seeks support for the collection of additional data from electronic GP records for patients included in the non-consented surveillance arm of the study, as outlined in the amendment documentation. The additional data items are no more disclosive, and there is no change in data flow.

The amendment also sought support for research practitioners to send a text message to potential participants prior to phoning them. This would only apply to patients where the clinician has not sent a text message about the study and the text message will be the same as the message sent by clinicians. This will allow the patient to find out a bit about the study prior to the phone call and will mean that they are expecting a phone call from the research team. The study team might send a text to the patient but then fail to contact them by phone. As the text message only provides information about the study and does not seek the patient's consent, this would not be considered as 'non-response' and the patient could be included in the surveillance arm of the study.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair was content to recommend support for this amendment. The Chair noted that patients that had registered a National Data Opt Out were included into an anonymised dataset collected by the direct care team. This does not require 's251' support, and is accepted by CAG as notification only, although the Chair noted that the applicant should be reminded that all processing regarding these patients would need to be undertaken by the direct care team, and anonymised in line with ICO guidance. The Chair stated that the additional

data items are sensible, the non English speaking group should be included, and the text messaging was reasonable.

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 **21/22** DSPT reviews for **University of Bristol - Bristol Medical School (EE133799-BRMS)** and **NHS Bristol, North Somerset & South Gloucestershire ICB** (to cover the 6 participating GPs), were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 09 June 2023).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 30 May 2023**

21/CAG/0157 – CVD-COVID-UK/COVID-IMPACT: UK-wide linked routine healthcare data to address the impact of cardiovascular diseases and other health conditions and health-related risk factors on COVID-19 and the impact of COVID-19 on cardiovascular diseases and other health conditions

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to understand which patients with pre-existing conditions are most likely to be affected by Covid-19 infection. 's251' support allows the disclosure of confidential patient information from the legal entities of the unlinked datasets listed on the Trusted Research Environment (TRE) dataset provisioning dashboard to NHS England (for English data) or the Trusted Third Party of the SAIL databank (for Welsh data).

This amendment sought support to extend the duration of 's251' support from 1 June 2023 to 31 December 2024, to enable studies using the data to conclude.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed: Due to the number of participating organisations involved it is the responsibility of Health Data Research UK as controller, to ensure that participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised**

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 09 June 2023

23/CAG/0082 - The Prognostic Performance of the Enhanced Liver Fibrosis Test in UK Patients with Chronic Liver Disease Assessed 20 Years After Recruitment to the EUROGOLF study (EVenti).

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This submitted information represented a new application in relation to an existing activity under application reference 20/CAG/0122. As a result of NHS England (previously NHS Digital) requesting that controllership be amended, the main change is that of a change of data controller, from solely Royal Free London NHS Foundation Trust to solely University College London. The Chief Investigator remains the same.

In addition, the applicants wish to update CAG with regards to the fact that health-economic analysis is now included in the data analyses, the Trial Co-ordinator is changed, and the Trial Statistician is changed to a member of UCL staff who has access to the UCL Data Safe Haven. Associated updated protocol, data flow diagram, and patient notification documents are provided.

The applicant has also informed CAG of other changes to the application as part of this new controllership amendment; All references to 20 years of follow up have been changed to 23 years of follow up, and 2020 as the censor date is replaced by 2023 as the censor year. All other changes relate to the change of data controllership.

The amendment supported in January 2022 to clarify that support is in place for study ID, NHS number, date of birth and gender to be disclosed from Royal Free London NHS Foundation Trust to NHS England (previously NHS Digital), in order for NHS England to supply the applicant with a dataset linked to Study ID, (but with NHS Number, date of birth and gender removed), is noted, and this is now changed to University College London.

As part of the original Regulation 5 support, NHS Digital is listed in the application as a data processor regarding the data sources Hospital Episode Statistics (HES), Cancer registry and ONS mortality data. Due to organisational changes outside your control, the data processor for this source has changed to NHS England. Therefore, this letter confirms Regulation 5 support has been updated for this application to continue using data sources Hospital Episode Statistics (HES), Cancer registry and ONS mortality data, with NHS England as the new data processor.

The intention is to replace 20/CAG/0122 with this new application (23/CAG/0082).

Confidentiality Advisory Group advice conclusion

It was noted that no other changes to people, purposes, data and flows were flagged to the CAG by the applicant. The annual review remains on the same cycle as 20/CAG/0122.

The Confidentiality Advice Team therefore recommended to the Health Research Authority that the activity be supported, subject to compliance with the standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from REC **Confirmed 23 April 2020 initially, and change given Favourable Opinion on 22 November 2022.**

2. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The 2021/22 NHS England DSPT reviews for **University College London - Data Safe Haven (**EE133902-SLMS) & NHs England were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 12 June 2023).

19/CAG/0198 – Evaluation of an aid to diagnosis for congenital dysplasia of the hip in general practice: controlled trial randomised by practice

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to determine whether use of a diagnostic aid for developmental dysplasia of the hip (DDH) reduces the number of clinically insignificant referrals from primary to secondary care and the number of cases of late diagnosis of DDH. 's251' support is in place to allow access to, and disclosure of confidential patient information from participating GP practices to the research team, working at Great Ormond Street Hospital for Children NHS Foundation Trust, and subsequent disclosure to NHS England (previously NHS Digital) for linkage with HES and transfer to the UCL Data Safe Haven.

This amendment sought support to increase the number of participating GP practices from 152 to maximum of 172 and to increase the number of months infants are recruited from 15 months to 18 months. The applicants do not wish to increase the number of individuals recruited, and these changes to additional data processors, and longer recruitment window, are to ensure the recruitment targets are met.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed: Due to the number of participating organisations involved it is the responsibility of Great Ormond Street Hospital for Children NHS Foundation Trust as controller, to ensure that participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 22 October 2022**

18/CAG/0185 – At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK (ARRISA-UK): A pragmatic cluster randomised trial with nested economic and process evaluations examining the effects of integrating at-risk asthma registers into primary care with internet-based training and support

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the University of East Anglia aims to assess whether care provided to patients with asthma, who are at greater risk of hospital admissions and dying from their condition, can be improved via a GP-practice led intervention. Support under the Regulations is currently in place to allow the disclosure of specified confidential patient information from participating GP practices in England to Harvey Walsh prior to onward disclosure to NHS England (previously NHS Digital) for linkage with HES and ONS datasets.

This amendment sought support to extend the duration of the study in order to complete verification checks on the dataset, as per the protocol. The revised end of study date is 31 October 2023.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. The CAT considered the duration request reasonable and in the public interest.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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 - NHS Digital and Harvey Walsh Ltd. have confirmed Standards Met grade on the DSPT 2021/22** (By check of the DSPT tracker 13 June 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed Non-substantial 23 May 2023**

ECC 1-04(b)/2010– AgeX (Evaluating the net effects of extending the age range for breast screening in the NHS in the NHS Breast Screening Programme in England from 50-70 years to 47-53 years)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study aims to evaluate the effectiveness of extending the age period for offering screening to women. This amendment sought support to amend the Chief investigator from Professor Julietta Patnick to Dr Toral Gathani. Names of other key investigators are also updated in the associated updated protocol.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 21/22 DSPT reviews for **University of Oxford – Medical Sciences Division – Nuffield Department of Population Health & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 14 June 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 14 June 2023**

20/CAG/0067 – Learning Disability Mortality Review (LeDeR) programme

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The Learning Disabilities Mortality Review (LeDeR) programme reviews the deaths of all people with learning disabilities (aged 4 years and over) in England. The activity was previously given support under reference 16/CAG/0056. A new application was given support in May 2020 as the controller for the application had changed from HQIP to NHS England.

This amendment sought support to change the data processor from King's College London -ROSALIND to King's College London - Computational Research, Engineering and Technology Environment (CREATE), as King's College London have changed their data management system.

The amendment also sought support to remove North of England CSU (0AR) as a data processor for the application, as the applicant confirmed they are no longer processing confidential patient information without consent and outside the direct care team for the purposes of LeDeR.

This amendment also sought support to alter the data flow with regards to linking to mortality outcomes. South Central and West Commissioning Support Unit (SCW) is a data processor of the LeDeR system on behalf of NHS England. SCW DSCRO Regional Processing Centre (hosted by NHS England) is a data controller of National Datasets (including the Civil Registration of Deaths dataset). Currently the applicants disclose confidential patient information outside of SCW in order to link to ONS mortality data, via DARS.

This amendment seeks to amend the data flow to an internal linkage within SCW DSCRO Regional Processing Centre. Please see below for steps:

1. SCW (hosted by NHSE) as a data processor for the LeDeR system, sends the LeDeR NHS numbers internally to the SCW Regional Processing Centre (where SCW is a data controller, hosted by NHSE).
2. SCW Regional Processing Centre as a data controller (hosted by NHSE) of the LeDeR data supplements the LeDeR data with the Civil Registration of Deaths dataset (ONS mortality data), of which it is also a data controller.
3. SCW Regional Processing Centre releases the identifiable Civil Registration of Deaths dataset (ONS mortality data) for the LeDeR patients under a DARS agreement to SCW.
4. LeDeR reviews are conducted as per the CAG support and published LeDeR policy.
5. Pseudonymised data from the LeDeR system is released to King's College London (KCL) Create and their sub-contractor, University of Central Lancashire (UCLan), for the service improvement analysis, as per the 20/CAG/0067 amendment in November 2021 and the pending DARS agreement.

This is requested to enable a more timely addition of the mortality data, and to enable a streamlining of the process.This new process is also more secure as it is internal to SCW/NHSE and data does not have to flow to and from ONS/DARS.

Confidentiality Advisory Group advice

The amendment requested was considered by the CAG Vice-Chair, who was content to recommend support for this amendment, noting it appeared to be less disclosive than the previously supported flow.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **University of Central Lancashire (EE133869-CBMS), NHS England (X24), King's College London - Computational Research, Engineering and Technology Environment (CREATE) (EE133874-CREATE) and South Central and West Commissioning Support Unit (0DF)** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 03 May 2023)

22/CAG/0156 – General Health Outcomes in Subfertile Men: a UK register-based cohort study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to establish whether men with known subfertility are at a greater risk of developing chronic malignant and non-malignant health outcomes compared to men from the general population. 's251' support is in place to allow the disclosure of confidential patient information from NHS England (previously NHS Digital), containing data obtained from HES, ONS, National Cancer Registration and Analysis Service (NCRAS) Dataset, the Personal Demographics Service and Civil Registration records, to the UCL Institute of Child Health.

The original study design intended to include 2 population controls per sub-fertile male, to be identified by NHS England (previously NHS Digital) matched for month and year of birth, region, and parity and link them to the same outcome datasets as the case cohort. However, NHS England (previously NHS Digital) have now informed

the applicant that they are no longer able to identify the control cohort due to limited resources and capacity within the organisation. The health and mortality outcomes of the case cohort will now be compared to the general population using national statistics. This modified design will limit the ability of the applicant to adjust for certain demographic factors such as socio-economic status, parity etc, however it will still allow the examination of rates stratified by age and gender and will, therefore, provide valuable information regarding health outcomes in sub-fertile males.

Therefore, this amendment sought support to amend the study design, to include sub-fertile males only, and remove 's251' support for the creation of a control group. This amendment will therefore decrease the amount of confidential patient information required for linkage, as identifiable information on the control cohort will not be required for linkage to hospital, cancer and mortality data.

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

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 21/22 DSPT review for **NHS Digital** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 11 May 2023)

   The applicant and a representative from the HFEA confirmed that support under s251 was not required for the HFEA to disclosed confidential patient information to NHS Digital for linkage.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 16 June 2016

22/CAG/0125 – Management of Patients with Chronic Liver Disease Admitted to Hospital as an Emergency

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice-Chair
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The overall aim of this study is to identify which characteristics of treatments and services for acutely ill people with CLD impact on care processes and outcomes, in order to improve the national organisation and delivery of care for all people acutely ill with chronic liver disease. The application has 's251' support to link together data from NHS England (previously NHS Digital), Intensive Care National Audit & Research Centre (ICNARC), and NHS Blood and Transplant (NHSBT) about 100,000 patients with Chronic Liver Disease (CLD). NHS England will identify the eligible cohort using Hospital Episode Statistics and ONS Mortality Datasets.

Initially, NHS Digital (now NHS England) confirmed that they would not be able to manage an opt out mechanism directly on behalf of this study. However the applicant planned to enable a study-specific opt-out, facilitated by the research team, who could then forward details on to NHS Digital, who would ensure that they are excluded from the de-identified dataset that is provided to the research team. This was confirmed by NHS Digital as a mechanism that would work. ICNARC have an opt out option and this will be respected. The National Data opt out (NDO) will also be applied.

This amendment sought support to remove the study specific opt out mechanism, as despite NHS Digital confirming this mechanism would work, the organisation is now NHS England, and they have stated they do not have capacity to apply an application

specific opt out mechanism to this dataset, despite it being managed via the applicant. Existing opt-outs for the ICNARC dataset will still be respected, and the National Data opt out will also be respected. The privacy notice has been updated to reflect this.

This amendment also sought support for ‘s251’ support to include patients who are potentially under 18, for two reasons. Either as it is unclear what age they are because the age at time of admission is missing. Or the inclusion of data from patients whose retrospective health data might be for when they were younger than 18, however the index event will always remain over 18. This is because as part of the original application, the applicants are requesting a historic ‘lookback’, the last five years of records of patients who were adults at the time of their chronic liver disease admission, which may include some of their records as children.

The applicant further explained the justification for this amendment; In the HES year 2017/18, during the period from December 2017- May 2018, there was a temporary change in the way records were submitted to SUS, which means that the applicants estimate 17% of records during that HES year that are relevant to the study may have age missing. This proportion is as high as 26% in some badly affected months. Whilst applicants cannot carry out analysis on these patients (due to missing age), it is important to be able to quantify the number of admissions/patients this is likely to represent. This is particularly important as one of the key study objectives is to assess trends in admissions over time. The historic lookback records are required to exclude any previous admission for chronic liver disease, as applicants want to identify and study the first hospital admission for chronic liver disease. Support is already in place for this data to be collected, however the applicants have requested this amendment to clarify that some of this data may be collected from a time when the patients were children.

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 request, noting that the same has been accepted for other application, as NHS England have confirmed that they are unable to apply a project level opt-out. Two other opt outs are still being applied.

With regards to the other changes, the Alternate Vice-Chair was content with the amendment request, as the index event is remaining within adult age, it was felt that it is acceptable to include those whose age wasn't clear at the time of the event and also relevant retrospective records that may be relevant to childhood history.

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 21/22 DSPT reviews for **Intensive Care National Audit & Research Centre, NHS Blood and Transplant, NHS England & London School of Hygiene and Tropical Medicine** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 19 June 2023)

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

20/CAG/0029 – Incidence of Chronic Recurrent Multifocal Osteomyelitis (CRMO) in the United Kingdom (UK) and Republic of Ireland (ROI)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from reporting clinicians to the applicants at the Cambridge University Hospitals NHS Foundation Trust.

A previously supported amendment gained ‘s251’ support to review all relevant radiological images taken within the surveillance and follow-up phases of the study. This will involve additional processing of confidential patient information. The process is as follows; scans (containing confidential patient information) will be sent to Addenbrooke’s Hospital temporary PACS archive (TRAD). An anonymised copy of the images will be created using a unique study identifier. The patient identifiable data will then be deleted from PACS.

However it became apparent on initial transfer requests to reporting hospitals radiological departments that the Image Exchange Portal (IEP) was not used in all circumstances (particularly in Scotland and ROI). Therefore a need for an alternative transfer method arose. The use encrypted DVDs to send images is an established data transfer method. Without the transfer of the images via encrypted DVD, the radiological image review data set would be less robust due to a smaller sample size and the objectives of the study for a UK and ROI review would not be met. This would then affect study outcomes in terms of improving diagnostic criteria when reviewing radiological images.

This amendment therefore sought support to allow the transfer of radiological images for the study review via an encrypted DVD in cases where the use of the Image Exchange Portal is not available at the reporting hospital. The previous support stated images would only be transferred via the IEP.

The amendment also sought support to include two further radiologists to the radiological review panel. The addition of the two radiologists to the review panel strengthens the review of the imaging data to provide opinion from a wider view.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice team (CAT), who raised no queries regarding this amendment, noting that although the DVDs are an additional method of disclosing confidential patient information, 's251' support is already in place for the flow of data between participating Trusts and Cambridge University Hospitals NHS Foundation Trust.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 21/22 DSPT review for **Cambridge University Hospitals NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 15 June 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 14 June 2023**

23/CAG/0021 – CSOR: Children's Surgery Outcome Reporting Research Database

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application is a research database containing data relating to children treated for necrotising enterocolitis (NEC), Hirschsprung's disease (HD), gastroschisis, posterior urethral valves (PUV), congenital diaphragmatic hernia (CDH) and oesophageal atresia (OA). 's251' support is in place to allow the disclosure of confidential patient information from participating NHS trusts to Oxford University Hospitals NHS Foundation Trust, onward disclosure to NHS England for linkage to HES, and the return of a linked dataset.

As part of the original application, applicants detailed that they would confirm that children are alive prior to communicating with their parents at key time-points. Applicants planned to use the NHS spine for this process. NHS England have recently developed a new service, the Communications Service, which would be more appropriate for this purpose. This amendment is sought to specifically cover the use of the Communications Service for checking children included in the CSOR research database are alive. In order to use to the Communications Service, the applicants also need to increase the frequency that identifiers are disclosed to NHS England, as the Communications Service is updated weekly. The applicants reason that the benefits of not sending a letter to a deceased participant outweigh the increased frequency of disclosure of identifiers. The updated data flows are detailed below, and in associated updated protocol.

(i) Weekly transfer of Study ID, NHS number and date of birth of all infants in the database who are not known to be deceased from the secure servers at the University of Oxford to NHS England's communications service using the NHS England Secure Electronic File Transfer System (or any subsequent replacement file transfer system approved/requested by NHS England).

(ii) NHS England will receive the data and use the Personal Demographics Service/Civil Registrations (Deaths) datasets to determine which infants in the cohort are alive and which have died.

(iii) Weekly transfer from NHS England to the secure servers at the University of Oxford of a file confirming which infants in the cohort were alive at the time of mortality checking, and which had died. File to be transferred using the NHS England Secure Electronic File Transfer System (or any subsequent replacement file transfer system approved/requested by NHS England).

This amendment also sought support to clarify that ‘s251’ support is in place for the disclosure of confidential patient information from Oxford University Hospitals NHS Foundation Trust to the University of Oxford. This process is described in the protocol and the IRAS application that was submitted for CAG review, however it was omitted form the CAG outcome letter. This amendment confirms that ‘s251’ support is in place to allow the disclosure of confidential patient information from participating NHS trusts to Oxford University Hospitals NHS Foundation Trust, and then onwards to NHS England for linkage to HES, and the return of a linked dataset to the Trust, as per original outcome letter. Where children are identified as new cases, the NHS number, date of birth and treating hospital will be transferred using an Application Programming Interface (API) to the secure servers at the University of Oxford, as per responses provided in CAT advice form. Therefore, ‘s251’ support is also required for the onward disclosure of confidential patient information to the University of Oxford, from Oxford University Hospitals NHS Foundation Trust.

Updated patient facing documents are accepted by CAG as notifications.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, as the requested flows of data have been previously supported, and the increase in frequency appears to be justified.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold **Confirmed: Due to the number of participating organisations involved it is the responsibility of University of Oxford as controller, to ensure that participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.**

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed no REC review required via email 14 June 2023

22/CAG/0010 – The Integration and Analysis of Data Using ARtificial InTelligence to Improve Patient Outcomes with Thoracic Diseases

Name	Capacity
Professor William Bernal	CAG Alternate Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating trusts to the Oxford University Hospitals NHS Foundation Trust, for the purposes of developing an Artificial Intelligence model to aid in the diagnosis of lung cancer in pulmonary nodules identified on CT scans performed as part of the NHSE Lung Cancer Screening Programme.

In this amendment, the applicants sought support to include national datasets from NHS England as additional data sources to ensure accurate outcome data. 's251' support will be required to disclose confidential patient information (NHS Number, Gender and Date of Birth) from OUH to NHS England for linkage to NHS England datasets, including Hospital Episode Statistics (HES), ONS Mortality data, Cancer Registration, and the Emergency Care Data Set (ECDS). 's251' support will also be required for the return of NHS Number alongside clinical data from NHS England to OUH to allow DART to correctly link the HES and DART data. The applicant has confirmed that the data received from NHS England datasets will be treated similarly to DART data, and will be anonymised at the end of the study and stored up to 10 years from the end of the study. The retention of anonymised data for 10 years does not require 's251' support.

Including HES data will benefit the public as it means DART will develop better lung cancer prediction models and identify those who would benefit most from screening. The tools developed would not be so robust if the HES data were not used.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Alternate Vice-Chair was content to recommend support for this amendment, and was content that the statements in the patient notification documents were sufficient for this new processing – for example, '*enabling an NHS research laboratory to link your health records'* and '*so we can link data received from different places'*. The Alternate Vice-Chair noted that this amendment is very much within the spirit and intent of the original application.

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 **2021/22** DSPT reviews for **Oxford University Hospitals NHS Foundation Trust**, **Oxford University** & **NHS England** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 14 June 2023).

   Due to the number of participating sites where confidential patient information will be accessed, support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 01 June 2023

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application originally gained support to link data from 130,000 children and adults with congenital heart disease with a number of datasets. A previous amendment gained support to update the dataset with data extracts involving an additional cohort, and to include new patients registered in National Congenital Heart Disease Audit (NCHDA) who have had their first procedure from March 2017, up to and including March 2021, or March 2022 if available, and to link NCARDRS (National Congenital Anomaly and Rare Disease Registration Service) data to NCHDA and ONS.

This amendment sought support to extend the duration of ‘s251’ support until 31 May 2024, in line with a costed extension.

In the previous amendment, the applicants gained ‘s251’ support to link 2018 NCARDRS data (already held at UCL) and 2019 NCARDRS data to NCHDA and ONS data. This amendment seeks support for 2020 NCARDRS data, as it is now available.

Applicants originally requested month and year of birth (not day), and age at procedures, hospital admissions etc. For the analysis of NCARDRS data, applicants are also requesting month and year of estimated delivery date for non-live births. Time points have been requested as age in gestation weeks if pre-natal events, and in days if post-natal events. This is no more disclosive than the original data items, as none of this data is confidential patient informaiton.

The life status fields applicants planned to request from ONS for linkage to NCARDRS, are available with the NCARDRS data itself and therefore will be requested within the

updated NCARDRS extract, rather than as a separate transfer of identifiers, linkage, and extract from ONS. This is less disclosive than the original design.

The original proposal for CHAMPION included looking at post-operative complications in adults. As a new purpose of the audit, applicants will now also work on the reporting and risk adjustment of postoperative complications in children.

The applicants have also provided updated associated study documents to CAG which are accepted as notifications.

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

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **University College London - School of Life and Medical Sciences, NHS England, and NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM) & Redcentric (Harrogate**) (regarding NCHDA data at NICOR), were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 14 June 2023)

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

19/CAG/0198 – Evaluation of an aid to diagnosis for congenital dysplasia of the hip in general practice: controlled trial randomised by practice

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

Context

Amendment request

This application aims to determine whether use of a diagnostic aid for developmental dysplasia of the hip (DDH) reduces the number of clinically insignificant referrals from primary to secondary care and the number of cases of late diagnosis of DDH. 's251' support is in place to allow access to, and disclosure of confidential patient information from participating GP practices to the research team, working at Great Ormond Street Hospital for Children NHS Foundation Trust, and subsequent disclosure to NHS England (previously NHS Digital) for linkage with HES and transfer to the UCL Data Safe Haven.

This amendment sought support for the applicant to use the patient NHS number and date of birth in order to identify patients and link to the 2-year outcome at participating secondary care hospitals. This will be in addition to the linked HES data requested from NHS England. This is due to further discussions which have identified that the majority of outpatient data and diagnostic imaging data is not coded, and applicants would therefore not be able to capture a lot of the required outcome data via this route. Applicants, who are not considered direct care team, will now need to either individually attend each secondary care hospital and manually collect data from the site, or ask the site direct care team to provide the data of the patients referred to them from the GP practices enrolled onto the study. This is therefore a change to data processors, data sources, and data flows operating under 's251' support.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Alternate Vice-Chair was content to recommend support for this amendment, and noted that the patient notification documents provided are in keeping with this addition.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, 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: Due to the number of participating organisations involved it is the responsibility of Great Ormond Street Hospital for Children NHS Foundation Trust as controller, to ensure that participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised**

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

23/CAG/0024 – National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH) has support to collect confidential patient information for the NCISH core database on patients who died by suicide when under the recent care, or recently discharged from, specialist mental health services. ‘s251’ support is in place specifically to allow the disclosure of confidential patient information from the Office for National Statistics to NCISH, University of Manchester, the onward disclosure to the treating healthcare organisation, and the return of the completed questionnaire to NCISH.

This amendment sought support to continue to collect clinical data using an updated version of the NCISH questionnaire. The current version is April 2023. The proposed changes are to ensure that questions address ongoing concerns and are relevant to current clinical practice and policy, thereby continuing to assist with suicide prevention efforts. The questionnaire has been provided for review. This does not represent any change to any specific confidential patient information data item or data flow.

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 **2021/22** DSPT review for **National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH), University of Manchester** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 June 2023).

PIAG 4-08(b)/2003 - National Confidential Enquiry into Patient Outcome and Deaths (NCEPOD)

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes every year. This amendment covered the first of the reviews due to take place in 2023, which will identify and explore avoidable and modifiable factors in the rehabilitation of patients who have been admitted to critical care for more than three days. Following on from the COVID pandemic this is particularly timely and there is concern that the quality of care across the UK is not consistent.

The applicants aim to publish the results of the review late 2024.

Confidentiality Advisory Group advice

The amendment request was considered by Chair's Action. The Vice-Chair agreed that the amendment request was a straightforward amendment for NCEPOD to use its well-established methods to audit rehabilitation following critical illness as part of its regular programme, noting it was not an amendment of the methodology, but of the clinical work being audited. The Vice-Chair commented that NCEPOD is very well-established as one of the most effective audits undertaken in the UK, and was content to recommend support.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed – The NHS England 21/22 DSPT review for National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was confirmed as 'Standards Met' on the NHS England DSPT Tracker (by check of the NHS England DSPT Tracker on 16 June 2023)**

22/CAG/0014 – The Trauma Audit & Research Network (TARN)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

Support is in place for clinical teams at Trusts and Health boards (England & Wales) to input data (including identifiers) to the Trauma Audit and Research Network (TARN), at The University of Manchester for the purposes of national clinical audit. Support is also in place for NHS England and Digital Health and Care Wales (DHCW) to disclose confidential patient information linked to outcome data for all English/Welsh patients with specified trauma ICD 10 codes

to TARN, for the purposes of linking to TARN data, and for TARN to disclose this on to individual Trusts, for the purposes of validation.

This amendment sought support to include a further purpose into the current TARN application. TARN have been approached by the University Hospital Southampton to support them on a project titled ‘Selection of Patients for Early Intervention Following Blunt Splenic Injury using Machine Learning Models’ which aims to help develop a tool to provide consensus on which Non-operative management (NOM) patients would benefit from splenic artery embolisation (SAE).

The project would involve using an effectively anonymised dataset provided from the TARN database to validate and further refine a machine learning model in a larger cohort. University Hospital Southampton have developed the machine learning model to predict which patients would benefit from SAE. Based on sample calculation, they need 1500 patients to achieve precision of +/- 5% for specificity and sensitivity in the validation cohort and accounting for 10% incomplete patient data. The data that is required from TARN will include age, gender, time and date of incidence, mechanism of injury, and other clinical information, but no confidential patient information will be disclosed, and University Hospital Southampton will not be able to identify these individuals.

The project will not involve disclosure of any confidential patient information to University Hospital Southampton. However, TARN would be sharing data that had been collected under ‘s251’ for a different purpose to the original TARN application, hence the amendment request. The Privacy notice on the TARN website has been updated to reflect this work.

It is also noted that the applicants have amendment their ‘s251’ support on 22 December 2022 to include an additional purpose to the TARN application, of linkage of TARN data with STATS-19 data, by providing partial postcode to the Department for Transport (DfT). As part of this current amendment to ‘s251’ support, the applicants informed CAG that DfT wish to use the data for another project looking at Road safety Collisions and consequences, and the effectively anonymous TARN data will also be shared with a third party Business Intelligence Company (Point Sigma) who are working with DfT Road Safety Investigation Branch (RSIB). The data will be used to build up the intelligence function by using an AI-based approach to linking and obtaining insight from

data. It is hoped that this could provide new insight on road collisions and their consequences. This is accepted as notification with regards to the previously supported amendment.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. This amendment was discussed with the applicant prior to submission, and handling route agreed. The purposes of the TARN application have been amended accordingly.

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 **21/22** DSPT reviews for **The Trauma Audit & Research Network (J160), University of Manchester** (re data safe haven storage of HES and ONS data), **NHS Digital, Quality Health, and Medical Data Solutions and Services (MSDAS)** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 16 June 2023)

   Department of Health and Care Wales (DHCW) has a Caldicott Principles into Practice (CPiP) Out-turn report with a score of 97.5%, and improvement plan for 20/21 provided 9th June 2021.

   Due to the number of participating care providers involved it is the responsibility of TARN, as controller, to ensure that all organisations

disclosing confidential patient information to TARN meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

23/CAG/0022 – Infant Feeding Survey 2023

Name	Capacity
Ms Caroline Watchurst	HRA 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 applicant currently has 's251' support for the following cohort: "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 NHS Digital DARS processing times)." Two risks have been identified during an internal pilot that require mitigating actions from the applicant prior to the mainstage survey. Risk one – sufficient responses are not received across each questionnaire during the pilot survey. The mitigating action for this risk is to increase the sample size for the main survey. Risk two – NHS England are unable to supply the required data in line with the required timings for the survey. The mitigating action for this is to sample across two months and stagger the mail outs. In the event of these risks materialising, the applicant seeks 's251'support to allow the option to draw the sample from across two months (instead of one) of births from the Maternity Services Data

Set as a potential mitigating action. By extending the sample frame across two months, there is the possibility that the child or children may be up to one month older than stated in the original application when mothers receive their questionnaires.

The applicant currently has 's251' support for Gov.uk – Notify to send the SMS reminders encouraging participants to complete the survey. This amendment sought support to include an additional supplier listed on the application as a data processor – TextLocal, as an alternative option for sending out the SMS reminders. The justification for this is to ensures that should there be any service issues with Gov.uk – Notify, Ipsos has the option to quickly and easily switch supplier without impacting on project timescales. TextLocal is an approved and trusted supplier of Ipsos and operate the messaging service for a number of other Ipsos surveys.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no queries regarding this amendment, noting that these are mitigating actions that appear to be justified.

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 **21/22** 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 (15 June 2023)

3. Annual Review Approvals

CAG reference	Application Title
20/CAG/0001	Functional outcomes In Trauma (FIT) Study
22/CAG/0034	Artificial Intelligence Stress Echo (FINESSE)
ECC 5-04(b)/ 2010	Do hormonal treatments for assisted reproduction increase risks of cancer or mortality in women? A national cohort study.
ECC 4-03 (g)/2012	General Health & Hospital Admissions in Children Born after ART: A Population Based Linkage Study
21/CAG/0044	UK Longitudinal Linkage Collaboration
20/CAG/0151	NHS Digital and BAD: Dermatology Intervention Service and Clinical Registries
ECC 6-05(d)/2012	North west Clinical Outcomes Research Registry Database (NCORR)
21/CAG/0126	A retrospective cohort study to investigate body composition and survival in metastatic breast cancer
PIAG 1-05(j)/2007	A national population-based case-control study of the genetic, environmental and behavioural causes of breast cancer in men.
17/CAG/0058	National Chronic Kidney Disease Audit
PIAG 4-06(e)/2006	New Born Hearing Screening Wales (NBHSW) Evaluation
PIAG 6-06(c)/2008	valuation of the HPV Vaccination programme and its impact on the cervical screening programme
18/CAG/0185	At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK (ARRISA-UK): A pragmatic cluster randomised trial with nested economic and process evaluations examining

	the effects of integrating at-risk asthma registers into primary care with internet-based training and support
19/CAG/0223	TwinsUK: Phenotypic enrichment of the TwinsUK cohort through linkage to electronic health records and other databases.
15/CAG/0134	The risk of major bleeding with novel anti-platelets: A comparison of ticagrelor with clopidogrel in a real-world population of patients treated for acute coronary syndrome
18/CAG/0187	Project to Enhance ALSPAC through Record Linkage (PEARL): Phenotypic enrichment of the ALSPAC original parent/carer (G0) cohort through linkage to primary care electronic patient records and other databases.
18/CAG/0182	UK Prospective Diabetes Study (UKPDS) Legacy Study: long term follow-up of participants into electronic health records
15/CAG/0176	Predictors and prevalence of genital Chlamydia trachomatis infection and the impact of Chlamydia testing and treatment on sexual health outcomes
PIAG 2-10(f)/2005	Case Mix Programme
19/CAG/0055	Triage-HF Plus: Cardiac Implantable Electronic Device Remote Monitoring Combined with Telephone Triage to Identify and Manage Worsening Heart Failure
21/CAG/0108	What clinical outcomes are associated with the 'joint care' for teenagers and young adults with cancer? BRIGHTLIGHT_2021
ECC 8-05(f)/2010	A National Neonatal Research Database (NNRD)
22/CAG/0072	Out of Hospital Cardiac Arrest Outcomes (OHCAO)
22/CAG/0087	Out of Hospital Cardiac Arrest Outcomes (OHCAO)
19/CAG/0219	Epidemiology of Pancreatic Cancer Using Longitudinal Electronic Health Record Data
CR20/2014	Caerphilly ischaemic heart disease study, Speedwell study longitudinal study of ischaemic heart disease, mortality and cancer in Christs hospital school cohort

CAG 10-08(c)/2014	Intergenerational and life course influences on health and mortality.
CAG 1-03(PR2)/2014	1958 National Child Development Study (NCDS)
18/CAG/0041	Liverpool Lung Project
PIAG 1-07(e)/2004	British Women's Heart and Health Study
21/CAG/0047	Neonatal Intensive Care Data to be provided to the National Pregnancy in Diabetes Audit (part of the National Diabetes Audit NDA
20/CAG/0015	Clinical outcome modelling of rapid dynamics in acute stroke with joint-detail, remote, body motion analysis
20/CAG/0081	Predicting vascular complications in diabetes
19/CAG/0196	Evaluating prescribing safety indicators embedded in computerised clinical decision support software OptimiseRx
21/CAG/0081	neoWONDER: Neonatal Whole Population Data linkage to improving long-term health and wellbeing of preterm and sick babies
ECC 3-04(k)2011	UK Surveillance of Primary Congenital Hypothyroidism in Children
21/CAG/0085	Child Health Clinical Outcome Review Programme
ECC 2-06(n)/2009	National Cardiac Arrest Audit (NCAA)
18/CAG/0002	Trajectories of diabetes related health measures and subsequent health and educational outcomes
19/CAG/0109	Trajectories of diabetes related health measures and subsequent health and educational outcomes
22/CAG/0097	AGILE: Seamless Phase I/IIa Platform for the Rapid Evaluation of Candidates for COVID-19 treatment
18/CAG/0158	The Northern Region Young Persons' Malignant Disease Registry
CR17/2014	Epidemiological Study of BRCA1 and BRCA2 Mutation Carriers

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Dr Murat Soncul, & Ms Clare Sanderson, CAG Alternate Vice-Chairs	*14 July 2023*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*10 July 2023*