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

October 2023

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

1. New Applications

a. 23/CAG/0060 - Kids environment and health cohort

Name	Capacity
Ms Clare Sanderson	CAG Alternate Vice Chair
Mrs Sarah Palmer-Edwards	CAG Member
Dr Pauline Lyseight-Jones	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from UCL Great Ormond Street Institute of Child Health set out the purpose of creating a research database, a data resource which researchers will use

to study the links between school and home environments and children's health and education.

The health of children, as well as their cognitive development and associated school outcomes, are disproportionately affected by the physical environment in and around homes and schools. This includes their exposure to indoor and outdoor air pollution, busy roads and noise, and access to green and blue spaces. The social environment of the local area, including availability of local services, such as nurseries, and exposure to fast food, or gambling outlets may influence child health and development. The applicants seek to create a research database, containing data on all children born in England from 2006 onwards. Information for the children's mothers will also be collected from hospital patient records and Census records. Both live births and still births will be included in the cohort, but only live born children will be followed up via linkage to health and education data.

Regulation 5 support is sought for the disclosure of confidential patient information (NHS numbers, dates of birth, sex and full postcode) from ONS to NHS England for linkage to Birth Registrations and Mortality data. The linked dataset will then be held within the ONS Secure Research Service. The research team at University College London will only have access to anonymised data.

The applicants also seek support for ONS to store PDS derived UPRNs and postcodes separately to the KITE cohort. Researchers, other than the UCL team, will be able to request linkage to external environmental data mapped to Unique Property Reference Numbers/postcodes to the cohort via UPRNs and/or postcodes from the PDS or birth registration. UPRNs & postcodes will be encrypted by ONS before placed in the SRS for linkage.

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

Confidential patient information requested

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

Cohort	The initial database will contain data from all infants born (both live and still births) in England between 01 January 2006 and 31 December 2023. The applicants estimate that 11 million children will be included in the database when

	created. Data for patients' mothers will also be required. The initial cohort will comprise approximately 22 million people. The database will be updated annually. Around 585,000 live births occur in England each year. Including both patients and mothers will mean around 1 million patients will be included in the database each year.
Data sources	1. Birth Registrations and Mortality data, Office of National Statistics (ONS) 2. Personal Demographics Service, NHS England
Identifiers required for linkage purposes	Infants: 1. Name 2. Date of birth 3. NHS number 4. Gender 5. Postcode 6. Unique Property Reference Number (UPRN) Mothers: 1. NHS numbers 2. Date of Birth 3. Postcode
Identifiers required for analysis purposes	1. Gender 2. Ethnicity 3. Age of mother at birth
Additional information	The applicants have clarified that patients' hospital number (i.e. the MRN number at individual trusts) is not needed for linkage.

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. Confirmation needs to be provided from ONS that the UPRN an item of confidential patient information.

The applicant provided confirmation that ONS consider UPRN to be an item of confidential patient information. The CAG noted this and raised no further queries.

2. The ONS need to clarify why patients cannot be identified to remove those who have registered dissent.

The applicants provided clarification from the ONS. The CAG noted this and raised no further queries.

3. A communications plan and patient notification materials need to be provided.

The applicants provided details of a Public Involvement and Engagement (PIE) Strategy, which has been reviewed by the ADR-UK Public Engagement Lead, and members of the GOSH BRC Young People's and Parents and Carers Advisory Group. The CAG noted this and raised no further queries.

4. The patient notification materials need to be clear on when the data processed is identifiable, pseudonymised and anonymised.

The applicants provided revised patient notification materials. The CAG noted this and raised no further queries.

5. Details of any further patient and public involvement undertaken need to be provided.

The applicants provided details on the further patient and public involvement undertaken. The CAG noted this and raised no further queries.

6. Details of the changes made as a result of feedback given during patient and public involvement need to be provided.

The applicants provided details on the changes made as a result of the further patient and public involvement undertaken. 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. Favourable opinion from a Research Ethics Committee. **Confirmed**

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

   The NHS England 2022/23 DSPT reviews for **UCL Great Ormond Street Institute of Child Health, the Office for National Statistics, and NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 03 October 2023)

b. 23/CAG/0100 - GP Management After Transition Events (GP-MATE) - Developing an intervention to assist older patients' communication with their GP practice after discharge from hospital in order to improve patient safety

Name	Capacity
Dr Murat Soncul	Alternate Vice Chair
Mr Thomas Boby	CAG Member
Dr Malcolm Booth	CAG Member
Ms Katy Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from the University of Warwick set out the purpose of medical research to produce an intervention to aid older patients in communication with their GP practice after discharge from hospital.

Discharge from hospital is a potentially risky stage of the patient journey, particularly for older patients who may have multiple morbidity and polypharmacy. Communication at the interface of secondary and primary care has been identified by the James Lind Alliance as one of the top three priorities for primary care patient safety. Clear communication via discharge summaries is essential in providing a safer discharge experience. Currently discharge summaries are designed for inter-professional communication, but patients have indicated their preference for receiving a copy of the discharge summary and want to be involved in conversations about their post-discharge care. The applicants seek to produce a tool, GP-MATE, to be used by older patients and their carers to aid communication with their GP practice about their care after discharge.

The study will take place over a four-year period. During the first year, a film will be made of patients experiences following discharge from hospital. In year two, three groups of patients and GP staff will create the GP-MATE tool. In the third year, the GP-MATE tool will be used at eight GP practices. Patients and staff will also be interviewed and surveyed. The records of around 300 patients will also be reviewed. In year 4, the findings will be drawn on to finalise the tool. Support under s251 is required to allow the research team to access the notes of all patients at the GP practices who are over 65 and have been admitted to hospital in the previous year. For the retrospective cohort, rates of readmission to hospital and links between the index admission and subsequent admissions will be investigated. For the prospective cohort, a weekly rolling search will be undertaken to identify all patients aged 65 or over admitted to hospital during the study period. The GP-MATE pack will be mailed out to suitable patients, and the research team will assist with the mail-out. Patients will complete and return the questionnaires, which will not be identifiable to the research team. The research team will collect data from the GP records of all patients in the prospective cohort from baseline (discharge) to 3 months after the GP-MATE consultation to determine: uptake, length and mode of appointment, and participating clinician's roles.

A recommendation for 1, 3, 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	PQDC - 300 retrospective cohort, 300 prospective cohort, anticipated 150 questionnaire cohort (50% response rate) 24 patient/carer interviewees (100% overlaps with PQDC prospective cohort). Retrospective cohort: patients treated between 01 July 2022 and 30 September 2023. Prospective cohort: patients treated for a 9-month period from 01 November 2023 to 31 July 2024.
Data sources	1. The electronic healthcare records and appointment systems at participating GP practices.
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Date of death
Identifiers required for analysis purposes	1. GP practice 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.

Number	Action required	Response from the applicant
1.	Clarify why collecting prospective patient consent is not practicable.	Applicants require access to patient healthcare records without consent in order to collect unbiased data on practices' use of the GP-MATE intervention with patients. The cohort of patients are particularly difficult to consent because they have recently been acutely

		unwell (in hospital) and many of them will lack capacity. It is often challenging to find somebody to act as a personal consultee for these patients who are more likely to be newly or acutely confused, and this impairment may well not be documented in their GP records. Furthermore, if the study only looked at individuals who are able to consent, applicants would miss a disadvantaged portion of the population who may benefit from having the intervention. The intervention also needs to be evaluated at a practice level, and therefore will need to be offered to all participants regardless of their ability to consent. Applicants need all the patients at the practice to receive the GP-MATE intervention in order to generate the numbers of patients required for the study. The practice essentially consents of behalf of their patients to use the GP-MATE intervention. In doing so, this minimises the burden on the patient/carer, who can choose to use the intervention without having to engage with the study commitments. A further complexity is introduced with the timing of GP-MATE – the intervention ideally needs to be offered in the 1st week after discharge, there simply isn't time to consent people prior to the GP-MATE appointment. Applicants also really need to study the population of patients who are invited but don't come to their GP-MATE consultation to understand why they don't make use of the intervention. CAG were content with this response.
2.	Ensure that the local opt out is clearly explained amongst the patient notification materials.	If the patient is in the prospective cohort, they will receive a pack in which an opt out form will be included. If the patient is in the retrospective cohort, patient notification materials will be displayed on the practice website and waiting room. The poster clearly explains methods that are appropriate to someone viewing it face to face and the website information contains opt out

		information that is more appropriate for someone viewing it online. The study website, which has been signposted to on both the poster and the website information, has been updated to include a section on “To find out more about **testing** GP-MATE, including how we'll be collecting information from **clinical records** and how to **opt out** please click here**”** Clicking on this link provides patients with more information on how to opt out and includes a link to the opt out poster. This can be found at: Testing GP-MATE (warwick.ac.uk) CAG were content with this response
3.	Create a second website page where the information displayed is in a lay friendly language which is more accessible to the lay reader.	A website page has been created titled “GP-MATE in plain English” where the information is much more accessible to the lay reader. This can be found at: GP-MATE - Research Progress (warwick.ac.uk) The link is accessed via the homepage GP-MATE (warwick.ac.uk) that is currently advertised on all patient notification material. It has been signposted to using the following: "To read more about GP-MATE, including a plain English summary, please click here" CAG were content with this response
4.	Ensure that the new website page clearly explains where confidential patient information is coming from, the process of how the information is being sampled as well as clarification on how people might opt-out via the local opt-out.	A new website has been created where all of this information has been illustrated in the form of a flow map. The diagram clearly shows how the research team will be accessing confidential information and when patients are able to opt out. The poster with more details about opting out has also been included on this new webpage. This can be found at: Testing GP-MATE (warwick.ac.uk) The link is accessed via the homepage GP-MATE (warwick.ac.uk) that is currently advertised on all patient notification material. CAG were content with this response

5.	Confirm the age limit for the cohort.	The applicant confirmed this is Patients ≥ 65 years of age and CAG were content with this response.
6.	Clarify how and when the research team will exit from section 251 support.	The research team will exit from Section 251 support by 31st January 2025. Deidentification of patient information is the exit strategy – no patient identifiable information will be collected after this date and all information that has been collected will be deidentified by 31st January 2025. This date will provide the research team with approximately six months to extract deidentified confidential patient information from 31st July 2024 (the upper limit of when the final patients from the prospective cohort will be recruited). A duration amendment will be required should this timeline require an extension. CAG were content with this.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 07 January 2023.**

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

   The NHS England **2021/22** DSPT review for University of Warwick was confirmed as 'Standards Met' on the NHS England DSPT Tracker.

c. 23/CAG/0096 - Clinical and cost-effectiveness of a maternity quality improvement programme to reduce excess bleeding and need for transfusion after childbirth: the Obstetric Bleeding Study UK (OBS UK) Stepped Wedge Cluster Randomised Trial

Name	Capacity
Dr Martin Andrew	CAG Member
Dr Tony Calland MBE	CAG Chair
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from Cardiff and Vale Health Board and Cardiff University set out the purpose of medical research that seeks to test the effectiveness of the Obstetric Bleeding Strategy intervention in treating excess bleeding during childbirth.

Excess bleeding is the most common complication of childbirth. Every year about 50,000 women in the UK lose 1L (2 pints) of blood or more. Many women need a blood transfusion or are admitted to intensive care and find the experience of bleeding traumatic, developing mental health issues after having their baby. There is a lack of knowledge about how best to treat the excess bleeding and, despite comprehensive national guidelines being in place, outcomes have not improved over the last 10 years.

The applicants have developed the Obstetric Bleeding Strategy (OBS). The strategy includes an assessment of every woman's bleeding risk, the real-time measurement of blood lost after all births, a consistent approach to managing excess bleeding and bedside tests to rapidly identify and treat abnormal blood clotting. This would be a change to current UK guidelines, which recommend measuring blood loss only after excess bleeding is identified. Confidential patient information will be extracted from patient records at participating English NHS trusts by members of the local research team. The confidential patient information will be disclosed to Cardiff University and collated into the OBS UK database. Confidential patient information will then be disclosed to NHS England for linkage to national datasets, and the return of the linked dataset to Cardiff University. A pseudonymised dataset will be held within SAIL – in order for data to enter SAIL, all identifiable data will be disclosed Digital Health and Care Wales, as the trusted third party processor. There are no

participating sites in Wales. There are 3 sites in Scotland, and 1 in Northern Ireland, but these are outside scope of ‘s21’ support.

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	189,000 Total international sample size (including UK). Patients will be recruited from 32 NHS maternity units in England. All women giving birth in these units will be included. The applicants estimate that 235,200 patients in England will be included.
Data sources	1. NHS England - Hospital Episode Statistics, Maternity Services Dataset, Children and Young People's Health Services Dataset, Child Health Surveillance System 2. Data provided from participating maternity units, disclosed to Cardiff University and collated in the OBS study dataset.
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level 2. 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.

#	Action required	Response from the applicant
1.	Clarify how you would manage the overlap of cross border postcodes between England and Scotland. Furthermore, explain whether the postcode would be retained and used within analysis.	Data from NHS England, eDRIS and Northern Ireland equivalent will be requested by individual hospital site level, of those sites participating in OBS UK. Applicants do not have any sites which are near the border, therefore do not anticipate any overlap of cross border postcodes. Applicants want to retain the postcode within the dataset and use it within the analyses. This is because it is known that significant inequalities occur in maternal and fetal outcomes in those individuals from socially deprived communities. If applicants retain the postcodes of individuals who deliver within the study period, they will be able to evaluate the effectiveness of the PPH care package, across all communities in the UK. CAG were content with this response.
2.	Clarify why the identifiers must initially pass through Cardiff University instead of being sent directly to the national process organisation.	To avoid identifiers coming to Cardiff University, applicants have specifically asked NHS England if it would be possible to setup a database, to sit within NHS England, which the research practitioner (NHS staff at hospital site) enters the identifiers required for linkage. They have not received a response. However, in previous studies, applicants have adopted the process suggested in the application, whereby the research practitioner (NHS employee) enters the identifiers (NHS number and postcode) on to the CTR study database, held on Cardiff University secure servers. The database is set up to ensure that identifiers are stored in a separate encrypted file, only accessible to the data manager, and completely separate to the 'clinical' data collected. CAG were content with this response.

3.	Clarify the use of Welsh data within the study and how the research team intend to use it.	Welsh data will only be collected as part of the process evaluation, which is not in scope for 's251'. This data will be collected via ethnographic observations and qualitative interviews with clinical leads, maternity staff and mothers (5-6 staff interviews, 2-3 patient interviews, per site, 4 sites). This part of the study will examine experiences of implementation of the care bundle using QI methodology during the pilot study (previously conducted, titled OBS Cymru) and how this worked overtime. Since it will be 4 years since the pilot study was conducted, exploring how PPH management occurs now, including if there are process changes and staff insights, will be useful to understand longer term sustainability, and help to anticipate barriers and optimise delivery of OBS UK. The CAG were content with this response, noting that it seemed therefore that Welsh data was not used as part of the scope of 's251' support.
4.	Continue engagement with the patient and public engagement and involvement group, and provide feedback to the CAG on their discussions regarding the use of confidential patient information without consent.	Applicants have engaged with their PPI advisory group, comprised of 8 members of the public who have experienced a PPH (7 mothers, and 1 father). In this engagement, they followed the same format as detailed in the original application, with 2 PPI co-applicants, both of whom experienced a PPH. Namely, applicants reminded the group of how they plan to use confidential patient information without consent, explaining how this involves routinely collected data, and data collected from individual health records. Discussions with those able to attend an online meeting revolved around four specific questions. Those unable to attend the meeting answered the questions via email. The questions and discussion/responses were provided to CAG for review. In addition to this recent engagement, applicants will continue to ensure that conversation about using data without individual informed consent is embedded within work with Egality Health and their community networks. Egality Health will oversee all patient facing materials, to make sure they are appropriate for different communities. They will also be producing a video, available in several languages, as well as English, that explains how data is being collected and used without consent in the study. These videos will be made available via maternity services social media/website.

		CAG were content with this response.
5.	Clarify the intention to access the Hospital Episode Statistics (HES) database. Furthermore, clarify what the research team would be investigating.	Applicants plan to use HES data to generate hospital cost profiles for each trial participant with the view to generating within-trial cost-effectiveness estimates. The cost-effectiveness of the Obstetric Bleeding Strategy PPH care bundle will be expressed in terms of incremental cost per confirmed case of red blood cell transfusion avoided. In order to inform a cost calculus, applicants plan to extract diagnostic codes, procedures codes and length of stay data for trial participants in order to estimate hospital costs up until hospital discharge for all trial participants. In addition, the HES dataset, in conjunction with MSDS, and Child Health data set will provide clinical details following a participant's PPH, which will allow applicants to answer secondary outcomes. CAG were content with this response.
6.	Please amend the following within the patient poster: a. Amend the colour and structure of the poster. b. Promote the use of the local opt-out whilst still respecting the NDOO.	The applicants provided an updated poster which the CAG were content with.
7.	Clarify whether special provisions are in place for those participating under the age of 16.	In maternity care young women under the age of 16 receive care from specialist midwives or midwifery teams who have particular expertise in ensuring their individual needs are met, including when necessary, ensuring they are aware of the legal rights. At each study site the study research midwife will ensure that the midwives who provide care to young women under the age of 16 are made aware of the study and opt out processes for the OBS UK study and bring this to the

		attention of the young women in their care. CAG were content with this response.
8.	Clarify why the participants post code was sought, and at what point this would be removed from the data.	The postcode is being sought for two purposes 1) to maximise the matching process when the data is linked and 2) to evaluate the effectiveness of the PPH care package, across all communities in the UK. It is known that individuals from socially deprived areas, have poorer maternal and fetal outcomes, therefore a useful study outcome would be to understand the effectiveness of the care package across all communities in the UK. CAG were content with this response.
9.	Clarify why the patient's name was retained.	The participant's name and contact details (including name, address, email address and telephone number) will only be retained for those participating in the psychological and health economic sub-studies. These personal details will be stored separately from the clinical data, in encrypted files, only accessible by the researcher who needs to contact participants to arrange interviews, and to send out questionnaires. Participants will be asked to provide consent for their contact details to be kept in this way, in order to facilitate the sub-study data collection. CAG were content with this response.
10.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	This was issued as per standard condition of CAG support.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 05 October 2023**

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

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

d.

23/CAG/0138	**A qualitative investigation of a novel Parkinson's Disease Hub: an integrated multidisciplinary service for patients with Parkinson's and related disorders with rapidly declining condition or unmet palliative needs**
Chief Investigator:	Dr Elisabeth Grey
Controller:	University of Bristol
Application type:	Research

Present:

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Mr David Evans	CAG Expert Member
Mr Andrew Melville	CAG Lay Member

Also in attendance:

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

Summary of application

This application from University of Bristol set out the purpose of medical research that aims to understand how the Parkinson's Disease (PD) Hub is experienced by people with PD, their informal carers and service providers.

Standard NHS care for people with PD has been criticised for detecting worsening condition too late. This can result in patients having to go to hospital for long stays when, had they been seen by a specialist sooner, their condition would not have become so bad as to need in-patient hospital care. A new service in North Bristol NHS Trust – the PD Hub - aims to ensure that people with PD whose condition rapidly gets worse are seen quickly by specialists and receive appropriate treatment, so that they do not need to be admitted to hospital.

A researcher is undertaking research using a number of different methodologies at Bristol PD Hub, including consented interviews 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 multidisciplinary team (MDT) meetings. Support under Regulation 5 is required for this aspect of the study as the applicant may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes or audio recorded voice notes. Identifiable patient information will not be recorded, and audio recordings will not be made of the meetings directly. The researcher will aim to make approximately 12 visits to the clinic over the course of nine months. MDT online meetings are also held online once a week. The researcher will aim to join approximately 15-18 of these meetings during the nine months.

Confidential information requested

Cohort	Patients who were discussed during multidisciplinary team (MDT) meetings of a Parkinson's disease service in North Bristol NHS Trust
Data sources	Multi-disciplinary Team (MDT) Meeting observations, recorded via written field notes, at North Bristol NHS Trust
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 linkage 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.

Number	Action required	Response from the applicant
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	REC FO was provided on 30 October 2023.

Condition of support

As part of the provisional outcome, the CAG also set out the following provisional specific conditions of support in addition to the standard conditions of support.

Number	Condition	Response from the applicant
1.	Please update the patient notification materials as follows, in line with advice in this letter, and provide to CAG for review; a. Add a statement to explain why 's251' support is required. b. Add a statement to state that 'section 251 support' was provided by the Health Research Authority (HRA), on advice from the Confidentiality Advisory Group (CAG).	This was completed by the applicant as per CAG advice, and met on 5 October 2023. It will therefore not be a condition of final support, as the applicant has already met the condition.

Confidentiality Advisory Group advice: Fully supported

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 30 October 2023**

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

   The NHS England **22/23** DSPT review for **North Bristol NHS Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 31 October 2023)

2. New Amendments

22/CAG/0075 – Clinical and Radiographic outcomes of reverse shoulder arthroplasty performed with 36-mm CoCrMo vs 40-mmcross-linked UHMWPE glenospheres at minimum 2-years follow-up.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

Support is currently in place to allow the direct care team to provide NHS numbers of the patients meeting the eligibility criteria to the research delivery team, and for the research delivery team to subsequently access medical records to extract clinical data.

This amendment sought support to extend the duration of 's251' support from 30 April 2023 to May 2024, to allow more time to recruit the cohort required, in order for the dataset to be sufficient to provide a clinically relevant analysis.

Also in order to ensure the relevant numbers of patients were recruited, this amendment also sought support to include Royal Berkshire NHS Foundation Trust as a participating site, and new data processor for the study.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT reviews for **Wrightington, Wigan and Leigh NHS Foundation Trust and Royal Berkshire NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 06 October 2023)

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

22/CAG/0055 – Near Fatal Asthma in Children and Young People

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has ‘s251’ support to allow the disclosure of confidential patient information by reporting clinicians at hospital trusts and health boards who are part of the PERUKI network to the University of Dundee HIC safe haven server, and the disclosure of confidential patient information to the chief investigator at the University of Edinburgh on questionnaires returned via email or by post. The study is investigating how often children aged 5-15 years in the UK and Republic of Ireland experience a near fatal asthma attack.

This amendment sought support to include Amazon Web Services (AWS) as a data processor the application, as the University of Dundee Health Informatics Centre (HIC) is migrating its servers to the AWS cloud service. The HIC safe haven will remain the main data processor storing the information, and the data will continue to be stored in the UK and managed by Dundee. However Dundee are moving the physical location of the data from onsite servers to AWS cloud storage which offers better security.

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. Security assurances are provided for the **University of Edinburgh and the University of Dundee**, in the form of an approval letter from the NHS Scotland Public Benefit And Privacy Panel For Health And Social Care, confirmed **23 September 2022**

   Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:** The NHS England 22/23 DSPT review for **Amazon Web Services** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 06 October 2023)

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

17/CAG/0020 – Clinical and Biological factors associated with relapse and length of survival following relapse in UK neuroblastomas

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This research study from Newcastle University is a retrospective epidemiologic and genetic study into Neuroblastoma, which is an embryonal childhood tumour derived from cells which go on to form the sympathetic nervous system.

The applicants currently have support under the regulations to allow the relevant data extraction at the identified sites to be undertaken by clinical data co-ordinators, who are not be part of the direct care team. The applicants also have support to further analyse the DNA of three children for whom consent has not been obtained.

This amendment sought support to extend the duration of the study until 30 September 2024, and the end of participant identification and data extraction is to be extended to 31 December 2023, to align with further funding secured. The amendment also is updating the study leaflets to reflect these changes.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT reviews for **Newcastle Upon Tyne Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 06 October 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed Non-Substantial 18 August 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 reduce the estimated sample size. The initial estimate was for applicants to recruit 21,888 infants, however 16,720 is the revised estimate.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment, and noted that this was now less disclosive than the original cohort estimate.

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 14 April 2021**

22/CAG/0066 – A pragmatic trial of an Artificial intelligence DRiven appOInTment maNagEment SyStem

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application seeks to investigate whether use of the DrDoctor appointment managing system increases the efficiency of patient appointments without compromising patient outcomes. 's251' support is in place to allow the disclosure of confidential patient information from participating NHS Trusts, Nottingham University Hospital Trust and Imperial College Healthcare NHS Trust London, and DrDoctor Patient Engagement Platform, to UKFAST Secure Cloud Data Storage at London South Bank University.

This amendment sought support to include Chelsea and Westminster Hospital NHS Foundation Trust as an additional participating site, and a data processor for this CAG

application. No data have been received from them at this stage, despite the REC amendment being processed in 2022. This is planned for October 2023.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 22/23 DSPT reviews **for Nottingham University Hospitals NHS Trust, Imperial College Healthcare NHS Trust, ICNH Ltd (DrDoctor), UKFAST, and Chelsea and Westminster Hospital NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 10 October 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 3 November 2022**

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

Name	Capacity
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.

The original ‘s251’ support for this study was to cover recruitment until the end of July 2023 with follow up until the end of October 2023. The study has secured further funding for recruitment to take place until the end of July 2024 with follow up until the end of October 2024. Recruitment will take place in the same form as the original application. The number of consented patients recruited to the study will be similar to that originally predicted as the level of recruitment has been less than originally calculated. With the additional year of recruitment, applicants anticipate reaching the original number of recruits. This amendment therefore sought support to extend the duration of ‘s251’ support until the end of October 2024.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT 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 10 October 2023).

2. Confirmation of a favourable opinion from a Research Ethics Committee**. Confirmed 29 August 2023**

23/CAG/0032 – Natural language processing of histopathology reports

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from University College London seeks to investigate use of natural language processing (NLP) in the analysis of histopathology reports. Support is currently in place to allow the disclosure of histopathology reports, which may include items of confidential patient information in the free text health data and demographic and clinical data, from participating NHS trusts to University College London.

This amendment sought support to include 3 new Trusts as participating sites and new data processors under ‘s251’ support. These 3 Trusts are Whittington Health NHS Trust, North Middlesex University Hospital NHS Trust and Homerton Healthcare NHS Foundation Trust.

Three of the existing approved study sites for this project (University College London Hospitals NHS Foundation Trust, Royal Free London NHS Foundation Trust and Barts Health NHS Trust) process the data required (pathology reports) for the 3 additional NHS Trusts (Whittington Health NHS Trust, North Middlesex University Hospital NHS Trust and Homerton Healthcare NHS Foundation Trust, respectively), as part of existing clinical service agreements. As the relevant data are already processed by existing study sites, there is minimal additional input required by these Trusts. Including data from these additional study sites will increase the power of the study (through increased sample size) thus potentially resulting in greater statistical and clinical significance of the findings.

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

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 20 September 2023

19/CAG/0104 – OPTIPREM: Optimising neonatal service provision for preterm babies born between 27 and 31 weeks of gestation in England using national data, qualitative research and economic analysis.

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 the National Neonatal Research Database held at Chelsea and Westminster Hospital NHS Foundation Trust to NHS England to link neonatal patient records to HES and ONS data, in order to determine if babies born at 27-31 weeks of gestation and admitted to a Neonatal Intensive Care Unit (NICU) show

improved survival and reduced major morbidity compared to babies admitted to a Local Neonatal Unit (LNU).

In this amendment, the applicants are seeking to extend the duration of support to 31 December 2027. The extension is required to accommodate delays in data analysis due to staff shortages.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no queries in relation to this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT reviews for **NHS England and Chelsea & Westminster Hospital NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 10 October 2023)

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

22/CAG/0002 – Assembling the Data Jigsaw in Greater Manchester: improving MSK research to advance patient care and inform patient policy using linked primary and secondary care data

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have support to allow the Business Intelligence Team at the Northern Care Alliance to access the Salford Integrated Record (SIR) dataset and link the dataset to an extract from hospital data sources to create a de-identified dataset for research purposes, and to retain access to the hashing algorithm, used to de-identify the dataset, until the study ends.

Due to delays, this amendment sought to extend the duration of support until 28 February 2024.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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:

   The NHS England **21/22** DSPT review for the **Northern Care Alliance** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 09 October 2023).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 24 August 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 datasheet, and an updated version of the datasheet checking protocol for services. These changes include the addition of an “email address of Consultant Psychiatrist” column to the datasheet. The NCISH administrative team will use this additional information to communicate via email from the ncish@nhs.net email address with the relevant clinician, for example to confirm patient contact or to ask any related queries. The datasheet will also now request the name and address of the current Team Manager of the team instead of the last staff member of the team who last saw the patient, if they cannot provide details of the Consultant Psychiatrist responsible for the patient’s care. Applicants have also made minor changes to the ‘NCISH datasheet checking protocol for services’ document to reflect these changes.

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 **2022/23** 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 12 October 2023).

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.

This amendment sought support for the inclusion of both the mother’s and baby’s postcode separately in the data shared by NHS England from the Maternity Services Dataset, to minimise the risk of contacting mothers who fall into the surrogacy, adoption, or foster categories. It is important that both the mother’s and the baby’s postcode is included to ensure that mothers who are no longer living with their baby are not contacted to take part in the survey.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and

therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

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

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

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.

This amendment sought support to include Civil registration – Deaths and demographics dataset as additional specified data sources (alongside HES). Linkage to these datasets by NHS England will provide the applicant with specific data items – date of death, sex, cause of death, age at death. Of these, only date of death is considered confidential patient information, and so this amendment sought support for this additional data item. Support is already in place for NHS England to provide a linked dataset back to the applicant, and this amendment is to include date of death in that 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 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 02 October 2023

20/CAG/0136 – A randomised controlled trial assessing the effectiveness and cost effectiveness of thrice weekly, extended, in-centre nocturnal haemodialysis versus standard care using a mixed methods approach: NightLife

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow potential incidental disclosure of confidential patient information when researchers from the University of Leicester, who are not members of the direct care team, carry out consented interviews with haemodialysis unit staff, consented interviews with patients, and observations on haemodialysis units at nine named NHS trusts.

This amendment sought support to include Liverpool University Hospitals NHS Foundation Trust and Norfolk & Norwich University Hospitals NHS Foundation Trust as new data processors for the application, as sites participating in Process Evaluation, workstream 2.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who determined that the applicants were correcting an error made in the original application.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed non substantial 18 September 2023**

2. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed**: **Security assurances are required for the sites where the observations take place. Support will be based on confirmation that the DSPT (or CPiP/Welsh IG toolkit for Wales) at the site will be complied with and that no identifiable information will be kept onsite or removed from the site. However, as this is more than 5 organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.**

22/CAG/0075 – Clinical and Radiographic outcomes of reverse shoulder arthroplasty performed with 36-mm CoCrMo vs 40-mmcross-linked UHMWPE glenospheres at minimum 2-years follow-up.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

Support is currently in place to allow the direct care team to provide NHS numbers of the patients meeting the eligibility criteria to the research delivery team, and for the research delivery team to subsequently access medical records to extract clinical data.

‘s251’ support is only in place for all patients treated with the SMR Reverse Shoulder System device (either with 36-mm CoCrMo (cobalt chromium molybdenum alloy) glenosphere or 40-mm cross-linked UHMWPE (ultra-high molecular weight polyethylene) glenosphere) at Wrightington Hospital between 01 January 2013 and 01 January 2020 where either:

1. The patient is deceased, or
2. The patient completed PROMs before February 2016.

A recent amendment to include Royal Berkshire NHS Foundation Trust as a participating site has been supported, however it was assumed that the recruited cohort would also be all patients treated with the SMR Reverse Shoulder System device (either with 36-mm CoCrMo (cobalt chromium molybdenum alloy) glenosphere or 40-mm cross-linked UHMWPE (ultra-high molecular weight polyethylene) glenosphere) at Royal Berkshire NHS Foundation Trust between 01 January 2013 and 01 January 2020 where either:

1. The patient is deceased, or
2. The patient completed PROMs before February 2016.

This amendment is to clarify that the scope of ‘s251’ support at Royal Berkshire NHS Foundation Trust covers all patients treated with the SMR Reverse Shoulder System device (either with 36-mm CoCrMo (cobalt chromium molybdenum alloy) glenosphere or 40-mm cross-linked UHMWPE (ultra-high molecular weight polyethylene) glenosphere) at Royal Berkshire NHS Foundation Trust, between 01 January 2013 and 31 March 2022 where either:

1. The patient is deceased, or
2. The patient completed PROMs and has a full data set and therefore does not need to be approached to consent for final follow-up

This is different to the relevant cohort at Wrightington Hospital.

This amendment also sought support to extend the cohort dates at both hospitals – changing from between 01 January 2013 and 01 January 2020 to now be between 01 January 2013 and 31 March 2022.

Both updates are made in order to meet the enrollment target. Additionally, Royal Berkshire Hospital do not offer patients local opt out from research on PROMs questionnaires as Wrightington Hospital did from February 2016, and therefore support

is needed for all data for eligible patients with complete data sets at Royal Berkshire Hospital to be collected without patient consent.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT reviews for **Wrightington, Wigan and Leigh NHS Foundation Trust and Royal Berkshire NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 13 October 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 13 October 2023**

17/CAG/0184 – UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)

Name	Capacity

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

Context

Amendment request

The amendment sought support for the RCPCH (with Microsoft Azure as a sub-processor), to administer the Epilepsy12 database, instead of Net Solving Ltd. The new data platform is scheduled to launch in 2023 to begin collecting data on patients in cohort 6. The Net Solving platform will remain active until January 2024 to allow users to continue entering data on cohort 5 patients up until the January data submission deadline. After this deadline, data entry will be paused on the Net Solving platform, however users will still be able to access and view their data but will not be able to make any changes.All data on the new platform will be hosted in servers within the RCPCH environment using Microsoft Azure as a sub-processor.

There will be a 2-month window between December 2023 and January 2024 where both platforms will be live and collecting data – cohort 5 data on Net Solving and cohort 6 on the new platform - before the Net Solving is 'switched off' for clinical data entry and archived.

Epilepsy12 will now only request that patients with a **confirmed new diagnosis of epilepsy** are entered onto the new platform. Currently, Epilepsy12 capture all patients with a suspected epilepsy diagnosis at registration stage. Additionally, the dataset has been minimized. The data dictionary has been updated accordingly and has been provided. The Epilepsy12 webpages will be updated accordingly to highlight the change in data platform. An updated data flow diagram has been provided.

Launching this new data capture platform for Epilepsy12 will facilitate more engagement in the audit by NHS Trusts and Health Boards. As all audit data is manually entered onto the platform, there is a data burden associated with audit participation. The new system is designed to be easier to use and navigate, which, when accompanied with a minimised dataset, will lower the time needed to enter audit data and reduce the burden for clinical teams.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Chair was content with the changes requested.

A DSPT for Net Solving Ltd will be required until they are no longer processing any confidential patient information without consent.

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 **22/23** DSPT reviews for **Net Solving Limited, NHS England, Microsoft UK, Royal College of Paediatrics & Child Health and SysGroup PLC** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 19 October 2023)

22/CAG/0071 – CompreHensive GeriAtRician led MEdication Review (CHARMER) - Work Package 3 Feasibility Trial

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 NHS medical records from participating sites, to Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH), and from there to NHS England (previously NHS Digital) to link to Hospital Episode Statistics, ONS Mortality data and NHS prescription data.

The amendment sought support to extend the duration of support from 31 August 2023 to 30 September 2025 in order to complete the linkage.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT reviews for **Northern Care Alliance NHS Foundation Trust, Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust, Norfolk and Norwich University Hospitals NHS**

Foundation Trust and NHS England were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 10 October 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 29 August 2023**

18/CAG/0063 – National Clinical Audit of Rheumatoid and Early Inflammatory Arthritis Clinical Audit

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

Context

Amendment request

This application from the British Society for Rheumatology (BSR) (commissioned by HQIP) set out the purpose of the National Clinical Audit of Rheumatoid and Early Inflammatory Arthritis (NEIAA). The audit aims to improve the quality of care for patients with Rheumatoid and early inflammatory arthritis (EIA) in England and Wales.

This amendment sought support to extend the duration of 's251' support until September 2025, as HQIP has awarded a 3 year extension to the BSR to run the NEIAA.

This amendment also sought support to extend the scope of the NEIAA, to include the following diseases:

- Early Inflammatory Arthritis (EIA)
    - Rheumatoid arthritis
    - Psoriatic arthritis
    - Axial spondyloarthropathy
    - Undifferentiated inflammatory arthritis

- Systemic Vasculitis
    - Giant cell arteritis
    - Large vessel vasculitis (not giant cell arteritis)
    - Anti-neutrophil cytoplasmic antibody-associated vasculitis
    - Small/medium vessel vasculitis (anti-neutrophil cytoplasmic antibody-negative)
    - Behcet's syndrome

- Connective Tissue Disorders (CTD)
    - Systemic lupus erythematosus
    - Primary Sjogren's syndrome
    - Systemic sclerosis
    - Idiopathic inflammatory myopathy
    - Undifferentiated/other connective tissue disease or overlap syndrome

NEIAA has been an important vehicle for improvement in care quality for patients with early inflammatory arthritis (EIA), however nationally there is increasing recognition of the importance of early treatment for other types of (rare) rheumatological immune mediated inflammatory diseases, many of whom will have inflammatory musculoskeletal (including arthritis) symptoms. The UK rare diseases framework recognises the need for improvement in the care people with these rare conditions receive and identifies four improvement priorities; priority one being to help patients get a final diagnosis faster. To support national priorities, NEIAA will now focus on the initial referral of all patients with any rheumatological immune mediated inflammatory disease (IMID), which includes rare IMID in addition to confirmed EIA. More in depth patient follow up will continue to focus on rheumatoid pattern arthritis. The aim this extended scope is to reduce diagnostic delay for patients with rare IMID.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Vice-Chair was content to recommend support for this amendment that will extend the duration of this audit to September 2025 and include further clinical conditions

within the audit. The inclusion of these clinical conditions is fully justified and will enhance the value of the audit.

It was also noted by the Confidentiality Advice Team, that the applicant had provided a DSPT review for King's College London (EE133874-CREATE). However as they appear to be a processor with regards to pseudonymous information only, which they have no means to re-identify, this means they are not a data processor with regards to this 's251' application, and no DSPT is required for the purposes of CAG. This DSPT should therefore not be listed in any future Annual reviews and amendments, unless they process any confidential patient information without consent.

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 **22/23** DSPT reviews for **Net Solving Ltd, and NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 06 October 2023)

   The Welsh IG team have confirmed security assurances **for Digital Health & Care Wales (DHCW)**

19/CAG/0059 – National Early Inflammatory Arthritis Audit Research Database

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

Context

Amendment request

This application from King's College London provides 's251' support for a research database from data collected under the National Early Inflammatory Arthritis Audit, which is commissioned by the Healthcare Quality Improvements Partnership (HQIP) as part of the programme of national audits, which operates with support under the Regulations via application 18/CAG/0063.

In line with the non-research application, this amendment sought support to extend the duration of 's251' support until September 2025, as HQIP has awarded a 3 year extension to the BSR to run the NEIAA.

This amendment also sought support to extend the scope of the NEIAA, to include the following diseases:

- Early Inflammatory Arthritis (EIA)
    - Rheumatoid arthritis
    - Psoriatic arthritis
    - Axial spondyloarthropathy
    - Undifferentiated inflammatory arthritis

- Systemic Vasculitis
    - Giant cell arteritis
    - Large vessel vasculitis (not giant cell arteritis)
    - Anti-neutrophil cytoplasmic antibody-associated vasculitis
    - Small/medium vessel vasculitis (anti-neutrophil cytoplasmic antibody-negative)

    - Behcet's syndrome

- Connective Tissue Disorders (CTD)
    - Systemic lupus erythematosus
    - Primary Sjogren's syndrome
    - Systemic sclerosis
    - Idiopathic inflammatory myopathy
    - Undifferentiated/other connective tissue disease or overlap syndrome

NEIAA has been an important vehicle for improvement in care quality for patients with early inflammatory arthritis (EIA), however nationally there is increasing recognition of the importance of early treatment for other types of (rare) rheumatological immune mediated inflammatory diseases, many of whom will have inflammatory musculoskeletal (including arthritis) symptoms. The UK rare diseases framework recognises the need for improvement in the care people with these rare conditions receive and identifies four improvement priorities; priority one being to help patients get a final diagnosis faster. To support national priorities, NEIAA will now focus on the initial referral of all patients with any rheumatological immune mediated inflammatory disease (IMID), which includes rare IMID in addition to confirmed EIA. More in depth patient follow up will continue to focus on rheumatoid pattern arthritis. The aim this extended scope is to reduce diagnostic delay for patients with rare IMID.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice Chair was content to recommend support for the extension of the duration of support for this research database and the inclusion of further clinical conditions within the database.

It was also noted by the Confidentiality Advice Team, that the applicant had provided a DSPT review for King's College London (EE133874-CREATE). However as they appear to be a processor with regards to pseudonymous information only, which they have no means to re-identify, this means they are not a data processor with regards to this 's251' application, and no DSPT is required for the purposes of CAG. This DSPT should therefore not be listed in any future Annual reviews and amendments, unless they process any confidential patient information without consent.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT reviews for **Net Solving Ltd, and NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 06 October 2023)

   The Welsh IG team have confirmed security assurances **for Digital Health & Care Wales (DHCW)**

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

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information between University of Leeds and Local NHS Trusts, EMIS, TPP, NHS England (previously NHS Digital/Public Health England), Department of Education and Department of Work and Pensions, to examine delays in diagnosis and long-term morbidity using routine NHS datasets. In a recent amendment, the applicants have 's251' support to include Patient Reported Outcome Measures (PROMs) as an additional data source, from Leeds Teaching Hospital NHS Trust (LTHT), and to change the research database hosting environment for YSRCCYP from University of Leeds-LASER, to AIMES. The transfer of data between the systems is gradual, and therefore security assurances are still required for both University of Leeds–LASER and AIMES until the transfer is complete. The applicant confirmed this is still ongoing.

This amendment sought support to clarify that University of Leeds will also be a data processor with regards to the supply of PROMS data, as applicants have identified that some PROMS measures have been captured as part of research studies. PROMs data alongside NHS number and/or hospital case number will be disclosed from University of Leeds to YSRCCYP, initially on a retrospective basis for patients already included in the register. For prospectively registered patients, University of Leeds will disclose PROMS data to YSRCCYP subsequently, once the patient's core dataset is registered. YSRCCYP will then link the self-reported PROMs data relating to the quality of life, psychological wellbeing, patient-reported symptoms, social wellbeing and functional status of patients to the existing YSRCCYP dataset. This will enable applicants to investigate the impact of these reported outcomes on survival and other disease outcomes (e.g. relapse, subsequent cancer/treatment) in the patient population. Applicants will also investigate variations in PROMs according to socioeconomic and ethnic differences. A revised data flow diagram has been submitted to reflect this new data source. The applicants also request 's251' support for the potential to capture PROMs data from any other NHS Trust or University in the UK holding PROMs data, for example if an individual attends a follow-up appointment at a centre outside of the Yorkshire Region. PROMs data will be included whether originally collected for research purposes or as part of standard patient care.

This amendment also sought support to extend the upper age range for inclusion of the first primary tumour from 29 years up to 39 years of age. This is to align with the international definition of Adolescent and Young Adult (AYA) cancers which now spans the 15-39 year age range.

The applicant has also informed CAG about updated patient notification documents, which have been accepted as notifications to CAG.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT). CAT clarified the security assurance requirements with the applicant, and raised no further queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT submissions for **University of Leeds – Laser, and AIMES were confirmed as 'Standards Met' by NHS England (by check of DSPT tracker on 16 August 2023).**

   Security assurances are required for the organisations where processing of confidential patient information will take place. Support will be based on confirmation that the DSPT at the site will be complied with. However, as this is 5 or more organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of University of Leeds, as data controller, to ensure that appropriate security assurances are in place. This includes NHS England (previously NHS Digital), EMIS, TPP, Department for Education and Department for Work and Pensions, and participating NHS Trusts, and University of Leeds with regards to PROMS data.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 24 August 2023**

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

Name	Capacity
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. An amendment supported 23 June 2023 covered the first of the 2023 reviews, 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 aimed to publish the results of the rehabilitation following critical illness review late 2024.

This amendment sought support to extend the duration of support with regards to this particular case note review - rehabilitation following critical illness, and to expand and move the sampling period.

Having undertaken some further scoping work the applicants have identified that:

1. The stated sampling period of one month (currently 1st Feb to 28th Feb 2022) for a pool of patients to sample from is too short. Applicants do not want to trouble hospitals at a later date for a second round of sampling if this is the case, and are therefore seeking support to extend the sampling period to three months.

2. Applicants also wish to move the sampling period to a later period than originally planned to ensure the data are as up to date as possible. The new three-month sampling period will be 1st Oct – 31st Dec 2022 inclusive and data on the follow-up will run until 31st Dec 2023.

In addition, the study is running later than originally planned by six months, this has been caused by the pandemic backlog. The timeline has been updated on the protocol.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed – The NHS England 22/23 DSPT 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 11 October 2023)**

21/CAG/0020 – The effect of age at first invitation for breast screening in the NHS Breast Screening Programme in England and Wales (AFBSS)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to establish whether the age at women are first invited for routine mammogram affects mortality from breast cancer. NHS England (previously NHS Digital) will link further death records and cancer registrations to flagged Age at first breast screening (ABFSS) patients originally flagged on the NHS Central Register (NHSCR), and supply the outcomes to the applicants who will link these data to the dataset they already hold on 1.4 million women born in 1945-1948 in England and Wales. ‘s251’ support is in place to allow NHS England to link further death records and cancer registrations between 31st December 2012 and 31st December 2019 from Civil Registration Mortality and Cancer Registrations Data to flagged ABFSS patients.

This amendment sought support to extend follow-up dates for linked data to the latest available data held by NHS England. This was originally requested up until 31 December 2019, however NHS England do not have the ability to perform a cut off date, and can provide data up until the current time point. This amendment has been requested by NHS England.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT), who agreed this was in the public interest.

The CAT noted that although the REC amendment also covers additional research questions, these are already supported by CAG as part of the final outcome, and this is detailed in the letter dated 10 August 2021.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 22/23 DSPT reviews for **University of Oxford - Medical Sciences Division - Nuffield Department of Population Health (**EE133863-MSD-NDOPH-NDPH) & **NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 11 October 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 16 October 2023**

20/CAG/0138 – Avon Community Acquired Pneumonia Study (Avon CAP): A Pan-Pandemic Acute Lower Respiratory Tract Disease Surveillance Study

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 North Bristol NHS Trust and University Hospitals Bristol and Weston NHS Foundation Trust to the University of Bristol, in order to determine population-based incidence rates of hospitalized adults ≥18 of age with community-acquired lower respiratory tract infection (LRTI - including Community Acquired Pneumonia) in Bristol.

This amendment sought support to extend the duration of 's251' support until the end of June 2025. The study funder has agreed to extend the study for a further 12 months. Recruitment will be extended by another year (with follow-up/data cleaning to end of June 2025).

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **2022/23** DSPT reviews for **University of Bristol (Bristol Medical School), University Hospitals Bristol and the Weston NHS Foundation Trust & North Bristol NHS Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 26 October 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 06 September 2023

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

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

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.

NHS England is the data controller of the LeDeR system. South Central and West Commissioning Support Unit (hosted by NHS England) is the data processor for the running of the LeDeR system on behalf of NHS England. South Central and West Commissioning Support Unit DSCRO Regional Processing Centre (hosted by NHS England) is a data controller of National Datasets (including the Civil Registration of Deaths dataset), and the linkage with these is undertaken 'in-house' as clarified by an amendment supported 16 June 2023. KCL (King's College London - Computational Research, Engineering and Technology Environment (EE133874-CREATE)) and UCLAN (University of Central Lancashire (EE133869-CBMS)) also process identifiable LeDeR data for the purposes of analysis for the LeDeR annual report.

This amendment is an administrative amendment to clarify which organisations are considered data processors for this application, with regards to undertaking the actual LeDeR reviews. Reviewers are either ICB employees, employed by a CSU contracted to deliver LeDeR reviews, or in rare cases employed by a private organisation contracted to deliver LeDeR reviews. Reviews could be undertaken by any of the 42 ICBs, or their contracted organisations, and will be dependent upon the geographical whereabouts of any individual included in LeDeR.

The applicant has therefore clarified that currently support is required for the following organisations to be included as data processors under LeDeR 's251' support, regarding:

1. North of England Commissioning Support Unit (NECSU)
2. South Central and West Commissioning Support Unit (SCWCSU)
3. Midlands and Lancashire Commissioning Support Unit (MLCSU)
4. All 42 Integrated Care Boards (ICBs)
5. Positive Behavioural Support Consultancy Ltd
6. Carehome Selection Ltd (T/A CHS Healthcare 0DS code A3EK)
7. Farley Dwek Solicitors Ltd

The amendment also requested for support for any new processor contracted in the future by ICBs, with the caveat that LeDeR should inform CAG via email notification when a new processor is included, and LeDeR should ensure the DSPTs have been reviewed as standards met by NHS England.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chairs' action. The Chair was content to recommend support for this amendment, and a new condition has been applied regarding informing CAG of any new processor.

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:**

   Due to the number of organisations involved it is the responsibility of NHS England, as controller, to ensure that all data processor organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

2. 'Section 251' support is in place for any new processor contracted in the future by ICBs for the purposes of undertaking a LeDeR review, however for each new processor, LeDeR should inform CAG via email notification when a new processor is included, and LeDeR should ensure the DSPTs have been reviewed as standards met by NHS England, as per standard condition of support.

18/CAG/0131 – Inflammatory Bowel Disease Registry

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

Context

Amendment request

The United Kingdom Inflammatory Bowel Disease Registry (IBD Registry) is a condition specific chronic disease registry established with the primary aim of supporting service delivery at point-of-care and facilitating audit and service evaluation at local and national level. The national IBD Registry has support to process

confidential patient information, in relation to all patients in the UK who had been diagnosed with inflammatory bowel disease (IBD). The application currently has 's251' support for NHS Trusts to upload confidential patient information via a web portal system, direct to the IBD Registry data management platform, hosted at AIMES, instead of to NHS Digital, and the dual system ceased being required in April 2022. 's251 support' is not required regarding consented patients.

This amendment sought support for the IBD registry to change their primary data hosting company from AIMES to Microsoft Azure. The applicants therefore request that Microsoft Azure be included in this application as a new Data Processor, to run alongside AIMES (as the existing Data Processor for the 'WebTool' service) until March 2024. After March 2024, when migration is complete, AIMES will be removed as a data processor for the application.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs Action. The Chair was content to recommend support for this amendment, noting that the justifications provided were 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 Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **22/23** DSPT reviews for **IBD Registry Limited**, **Civica - (previously CIMS), AIMES management service, & Microsoft** were

confirmed as ‘Standards Met’ on the NHS England DSPT Tracker (checked 19 October 2023).

DHCW has a valid CPiP Outturn report/Welsh IG toolkit.

22/CAG/0072 – Epidemiology and Outcome from Out of Hospital Cardiac Arrest (Research application)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to collect and summarise data to be used to improve outcomes of Out of Hospital Cardiac Arrests. ‘s251 support’ is in place to allow the disclosure of confidential patient information from participating NHS ambulance trusts to the University of Warwick for inclusion in the OHCAO database, and the disclosure of confidential patient information to NHS England for linkage to outcome data, and the return of the linked dataset to the University of Warwick.

The exit strategy for the retention of confidential patient information is one or more of the following three scenarios, either that funding for the registry is discontinued, the registry is no longer needed and replaced by data flows directly to NHS England, or after 11 years have passed.

The information provided in the original application with regards to the potential discontinuation of the registry funding was that the current contract ends in autumn 2023, although the funders have agreed in principle to extend funding in the longer term.

Funding is now confirmed as extended to 31 March 2024, and an application for a further 5 years in total (to 30th September 2028) is currently being assessed by the funders. Therefore this amendment sought support to confirm this duration extension, and update the exit strategy accordingly.

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:**

   University of Warwick Clinical Trials Unit and NHS England were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 27 October 2023).

   Due to the number of organisations involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation. These will not be individually checked by the CAT team due to the number of organisations involved.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 28 September 2023**

22/CAG/0087 – Title

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to collect and summarise data about people who experienced Out of Hospital Cardiac Arrests to be used to produce summary data for quality improvement work with ambulance services, charities and NHS England. 's251' support is in place to allow the disclosure of confidential patient information from participating NHS ambulance trusts to the University of Warwick for inclusion in the OHCAO database, and the disclosure of confidential patient information to NHS England for linkage to outcome data and the return of the linked dataset to the University of Warwick.

The exit strategy for the retention of confidential patient information is one or more of the following three scenarios, either that funding for the registry is discontinued, the registry is no longer needed and replaced by data flows directly to NHS England, or after 11 years have passed.

The information provided in the original application with regards to the potential discontinuation of the registry funding was that the current contract ends in autumn 2023, although the funders have agreed in principle to extend funding in the longer term.

Funding is now confirmed as extended to 31 March 2024, and an application for a further 5 years in total (to 30th September 2028) is currently being assessed by the funders. Therefore this amendment sought support to confirm this duration extension, and update the exit strategy accordingly.

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:**

   University of Warwick Clinical Trials Unit and NHS England were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 27 October 2023).

   Due to the number of organisations involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation. These will not be individually checked by the CAT team due to the number of organisations involved.

3. Annual Review Approvals

CAG reference	Application Title
18/CAG/0040	eLIXIR, Early Life course data Cross-LInkage in Research
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
CAG 8-03(PR11)/2013	Hip Fracture Audit
19/CAG/0117	IMS Health and HES Data Linkage
22/CAG/0128	Stroke Patient Reported Experience Measures (PREMS) Survey 2022
20/CAG/0095	Gender-specific outcomes post transcatheter aortic valve implantation
CR4/2014	Asbestos Workers' Survey
22/CAG/0022	Patterns of Multiple Long-Term Vascular Conditions: A pilot study
21/CAG/0048	STAMPEDE: Systemic Therapy in Advancing or Metastatic Prostate
21/CAG/0097	Predicting AF after Cardiac Surgery - the PARADISE Score. A Clinical Prediction Rule for Post-operative Atrial Fibrillation in Patients Undergoing Cardiac Surgery
19/CAG/0104	OPTIPREM: Optimising neonatal service provision for preterm babies born between 27 and 31 weeks of gestation in England using national data, qualitative research and economic analysis
21/CAG/0136	National Drug & Alcohol Treatment Monitoring System (NDTMS) & Criminal Justice Intervention Teams (CJIT)
22/CAG/0080	Cancer incidence and mortality in a cohort of women treated for subfertility in Oxfordshire and West Berkshire

17/CAG/0094	The assessment of risk and safety in mental health services
20/CAG/0073	Assessing the cancer risks due to occupational exposure to styrene
21/CAG/0148	Postoperative vasopressor usage: a prospective observational study. Relation to Perioperative Atrial Fibrillation (AF)
22/CAG/0117	NICOR Commissioning through Evaluation Registries/Audits
22/CAG/0059	The Whitehall II Study

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

Caroline Watchurst, Confidentiality Advisor *11 December 2023*