Health Research Authority

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

September 2022

1. New Applications

a. 22/CAG/0080 - Cancer incidence and mortality in a cohort of women treated for subfertility in Oxfordshire and West Berkshire

Name	
Dr Martin Andrew	CAG member
Dr Patrick Coyle	CAG vice-chair
Dr Sandra Duggan	CAG member
Mr David Evans	CAG member
Mr Tony Kane	CAG member
Mr Andrew Melville	CAG member
Mr Dan Roulstone	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Mr Michael Pate	HRA Confidentiality Advisor

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University of Oxford set out the purpose of medical research which aims to assess whether risk of cancers, in particular those that are definitely related to hormonal exposure, are altered depending on the cause of the woman's subfertility and/or the types of drug treatment she received for it, if any. Applicants will also look at whether the mortality risk differs from the general population, and whether the children born to the women following subfertility treatment have any different characteristics at birth.

Lifetime hormonal exposure is an important factor in many female cancers. Such factors include the timing of menstruation, pregnancy history, age at menopause, as well as use of oral contraceptives and hormone replacement therapy. For those experiencing difficulty conceiving, it is uncertain whether the medical conditions underlying subfertility, and/or the treatments used to aid conception, also alter risk. This study aims to investigate this.

This study began in 1992, with the appropriate permissions required at the time. No consent was taken for the data collection, following regulatory advice given at the time. Approximately 7000 women were included in the dataset. This data was linked to national records of cancer incidence and mortality, and embarkation/re-entry by OPCS/ONS National Health Service Central Register (ONS NHSCR), under 's251' support, (the general NHSCR application - **ECC 2-04(c)/2010**) until April 2013. The department was closed in 2014, and the data have been retained but not processed since this time. These were held with no specific legal basis under common law, but were retained in the public interest. The applicant now requires a refreshed 's251' application in order to access the data and anonymise for analysis, and this has been requested by NHS Digital, in order for the applicant to provide a legal basis for processing under common law, which is required to renew their data sharing agreement with NHS Digital.

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

Confidential patient information requested

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

Cohort	7000 women who were investigated for a subfertility problem between 1973-89, identified from; • records of infertility clinics in Oxfordshire and West Berkshire • maternity records held by the Oxford Record Linkage Study (ORLS) (definition of subfertility - failure to conceive despite adequate attempts to do so for up to 1 year, at the time of their initial infertility clinic consultation) Data already extracted between 1992 and 2000 by the research team.
Data sources	1. University of Oxford linked database of women as described above, linked to outcome data received until 2013 (from ONS NHSCR). – obtained under 's251' support as part of NHSCR application (ECC 2-04(c)/2010).
Identifiers retained, and required for processing in order to anonymise the dataset	1. Womens' forenames (and initials), 2. Womens' surnames at birth and subsequently, 3. Date-of-birth 4. Gender 5. NHS numbers 6. Hospital numbers 7. unique study number 8. Data received from NHS Digital up until 2013; a. Cancer Registration data b. Mortality records,

	c. records of embarkation and exit/re-entry to the NHS
Identifiers required for analysis purposes	1. N/A – applicant states analysis will be undertaken on an anonymous dataset

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

1. **Please develop a layered patient notification, which is more clear and accessible to lay people, using the guidance in this letter.**

The applicant has developed a notification for the cohort, which will be displayed in appropriate clinical areas in The Women's Centre (TWC) entrance hall of The John Radcliffe Hospital (JRH), and a privacy notice for the Nuffield Department of Women's and Reproductive Health (NDWRH) website. He has also drafted an article for a newsletter. The CAG were content with the notifications, stating these are now reasonably accessible, and accepting that the historical nature of this particular cohort would mean that any notification would be difficult to appropriately display, in order that those in the dataset may see it.

2. **Please undertake patient and public involvement, surrounding the use of confidential patient information without consent, and to review the newly developed patient notification materials.**

The applicant has undertaken Patient and Public involvement with 9 women, and completed 30 minute telephone interviews all 9. The women varied in age between 22-74 years, but mostly were aged between 60 and 74. The group appeared as representative of the cohort as possible. It appears some very valuable insights have been gleaned form these discussions, and the women agreed that they were supportive of the use of confidential patient information without consent for the purposes of this application. The individuals also provided feedback on the notification content and method, most of which the applicant has adopted. The Sub-Committee were content that this was good patient and public involvement with a representative group, and the applicant had thoroughly explored all that was requested. The CAG were now content to recommend support.

3. **Provide a favourable opinion from the REC, as per standard condition of support.**

This was provided on 08 September 2022, as per standard condition of support.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 08 September 2022**

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

The NHS Digital **21/22** DSPT review for **University of Oxford Medical Sciences Division (8HM11)** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 18 August 2022)

b. 22/CAG/0055- Near Fatal Asthma in Children and Young People

Name	
Dr Tony Calland MBE	CAG Chair

Dr Martin Andrew	CAG member
Ms Sophie Brannan	CAG member
Dr Sandra Duggan	CAG member
Professor Lorna Fraser	CAG member
Mr Andrew Melville	CAG member
Ms Diana Robbins	CAG member
Dr Murat Soncul	CAG Alternate Vice Chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from the University of Edinburgh set out the purpose of medical research that seeks to understand how often children aged 5-15 years in the UK and Republic of Ireland experience a near fatal asthma attack.

Near fatal asthma is the most severe form of asthma attack and the UK has the highest rate of asthma death for children in developed healthcare. Children who experience severe asthma attacks are more likely to subsequently die from asthma. Until recently, there was no agreed definition of near fatal asthma and the prevalence could not be estimated. The applicants recently created a definition using an international group of experts so that it is now possible to measure how frequently it occurs in our population. The closest estimate for the prevalence of near fatal asthma attacks is 200-250 children per year in the UK, based on admissions to paediatric intensive care with acute asthma. However, not all children who experience near fatal asthma will be admitted to intensive care and some intensive care admissions would not fit this definition.

The applicants will conduct a prospective epidemiological survey of clinicians in the UK and Republic of Ireland (ROI) using the British Paediatric Surveillance Unit (BPSU) Orange eCard system. This will be undertaken over 18 consecutive months with a

follow-up phase at 1 and 2 years of age. The BPSU 'Orange e-Card' has a list of rare disorders under active surveillance which is sent electronically every month to over 4,000 British and Irish consultant paediatricians and other specialities. Clinicians will return the Orange e-Card to the BPSU, notifying any cases seen or 'nothing to report'. The clinicians name and contact details will be passed to the study team and the reporting clinician will be directed to the study online questionnaire, which will request details on the presentation of near fatal asthma, demographic details, investigation and management. A further outcome questionnaire will be sent at one and two years following the near fatal asthma attack. The questionnaires will be run through the University of Dundee HIC safe haven server. If clinicians are unable to use the online system, questionnaires will be sent out in an electronic document format to the reporting clinicians via the investigator's secure nhs.net email account. As a last resort, a paper questionnaire form will be sent by registered mail. It will be marked confidential and double enveloped for data collection with self-addressed envelope to be returned to the chief investigator's office in the University of Edinburgh. Limited confidential patient information will be included so that duplicate cases can be identified. These items of confidential patient information will be removed as soon as possible and held separately to the anonymised dataset used for analysis.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Patients aged 5-15 years considered to have experienced an episode of near fatal asthma and who meeting any one of the following: • Survived an acute episode of asthma, with the following features: ○ Pulse oxygen saturation below 92% despite maximal oxygen therapy (i.e. 10-15l/min oxygen flow via non rebreath mask) during acute presentation

	○ pH <= 7.2 and/or pCO2 >=60mmHg or 8kPa ○ Escalation to use of intravenous bronchodilator infusion • Survived an acute episode of asthma and who had a respiratory arrest and/or required cardiopulmonary resuscitation as part of their presentation • Survived an acute episode of asthma for which they were invasively ventilated The applicants anticipate that 375 patients in the UK will be recruited and that the majority of cases will be recruited from England.
Data sources	1. Questionnaires completed by reporting clinicians working in emergency departments, and other clinical areas within the PERUKI network (Paediatric Emergency Research UK and Ireland). Clinicians in all clinical areas may encounter and report cases of Near Fatal Asthma (NFA) in CYP and complete questionnaires. This will include General Paediatric, Critical Care and Emergency Medicine doctors. Clinicians in Paediatric Critical Care Units will also be able to register cases via the same system as emergency clinicians (QR code with link to BPSU –HIC questionnaire)
Identifiers required for linkage purposes	1. NHS number 2. Hospital ID number 3. Date of birth 4. Date of death 5. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level 2. Gender 3. Ethnicity

Confidentiality Advisory Group advice

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

1. **The patient information leaflet requires revision to ensure that the study is explained as clearly and concisely as possible. Further details on how patients can opt-out also need to be included.**

The applicant provided an update. The CAG were content with the updated version provided, however the CAG recommend using the term anonymised rather than de-personalised in the patient leaflet. The applicant confirmed this would be changed.

2. **Provide confirmation that the confidential patient information collected will be deleted after two years.**

The applicant confirmed that this is proposed to be a maximum of three years and the CAG were content with the justification.

3. **Alternative means of detecting duplicate reports need to be explored. If no alternative is available, an explanation on why no alternatives can be used needs to be provided.**

In a call with HIC Dundee on 26.04.22, applicants explored the ability of the research team to be made aware of duplicate cases, without their exposure to identifiers (i.e. hospital number, date of birth). HIC Dundee will now provide the facility for researchers to identify duplicate cases without personal identifiers being visible. The CAG were content with this response.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 11 May 2022**

2. 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**

c. 22/CAG/0084 - Warrington Health and Wellbeing Survey 2022

Name	
Dr Harvey Marcovitch	CAG member
Ms Rose Payne	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Warrington Borough Council (WBC) set out the non-research service evaluation purpose of establishing a patient health and wellbeing survey in the region. The application will undertake a comprehensive, large scale survey of adult residents in Warrington to update the information currently held from previous local lifestyle surveys. The survey needs to collect information on a wide range of topics including; perceptions of health status, emotional wellbeing, social connectedness and resilience, long-term and recent morbidity, disability, health risk behaviour, use of services, social circumstances, and neighbourhood issues. Impact of the Covid-19 pandemic will be an additional topic in this survey.

Historically the survey facilitation team had been based within the public health department of the local Trust and had been able to facilitate the survey distribution locally without the requirement to seek support under the Regulations. Due to revision of local services, the survey distribution team was now hosted by the Warrington Borough Council, which has led to the changes in the survey methodology. ‘s251’ support is requested in order for a third party mailout company contracted by the

council, who are not considered direct care team, to facilitate the invitation of individuals in the area, in order for them to consent into the survey. NHS Digital will supply the third party mail out company with confidential patient information about the cohort. The council themselves will never have access to any confidential patient information.

Outcomes of the survey will be used for the following purposes:

- Inform Warrington's Health & Wellbeing Strategy, Joint Strategic Needs Assessment and underpinning strategies for council and partner organisations.
- Assist in health needs assessment, by providing up-to-date data on morbidity and health and wellbeing status,
- Assist in the commissioning and targeting of resources by highlighting areas/groups experiencing health inequalities,
- Provide information for monitoring health change and the impact of local prevention and health programmes, by repeating salient aspects of previous surveys where possible and practical.

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

Confidential patient information requested

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

Cohort	18+ adults living in Warrington and/or registered with a Warrington GP. (excluding prisons). Approximately 34,000 patients will be invited to participate, to aim to get 6,800 responses. 's251' support also requested for potential boost sample, approximate numbers will not be known until survey is underway.

Data sources	1. NHS Digital a) Primary Care Registration System
Identifiers required for the purposes of sending survey invitations	1. Name – title, forename and surname 2. Address – house name/number, street, post town, postcode 3. Sex 4. GP practice code 5. Date of birth 6. Unique ID
Identifiers required for analysis purposes	1. Age 2. GP Practice code 3. Sex 4. Postcode – modified to LSOA/OA level by NHS Digital The final dataset to be retained for analysis will be in pseudonymised form only, with no way for applicants to re-identify
Additional information	3rd party to hold a look-up list which matches unique ID to patient name and address to allow for respondent opt-out after completing the questionnaire If required, (if certain groups are underrepresented) WBC to contact NHS Digital to request a boost sample of additional patients to be sent a letter inviting them to participate in the survey.

Confidentiality Advisory Group advice

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

1. **Please confirm, after discussions with NHS Digital, if the data source required to extract the sample is the PDS (Personal Demographics Service).**

The applicant confirmed that the data source is the Primary Care Registration System, and the CAG were content with this response.

2. **Confirm which organisation would be acting as the third-party contractor to distribute the survey. Appropriate security assurances checks will need to be undertaken when this organisation is confirmed, in the form of a DSPT reviewed by NHS Digital.**

The applicant confirmed the third party mailout company will be Direct Data Analysis, who have a long standing partnership with another company, Central Mailing Services, to whom they contract out survey mail outs. Both DSPTs are in place.

3. **Please provide a revised poster and website notification, which clearly explain the processing activity as per the advice in this letter, and include details of the specific third party contractor. This should also have an opt out option.**

The applicant provided the updated documents, and the CAG were content with this.

4. **Please provide details of how the opt out mechanism will work.**

The opt-out process for invitation mail out will involve the resident contacting Direct Data Analysis by email or telephone to instruct that they do not wish to participate in the survey. Direct Data Analysis will then perform a check of the sample list once received from NHS Digital and ensure that no resident who has instructed removal is included in the mail out. Direct Data Analysis will be asked to ensure that a record is kept of those not wishing to participate to which they must refer in the event of any other reminder or boost mail outs in relation to this specific project. The CAG were content with this response.

5. **Further patient and public involvement should be undertaken, and include questions around the use of confidential patient information without consent, and provide feedback to the CAG.**

As part of the patient and public engagement and involvement process, and following advice from the CAG, a consultation exercise was undertaken with residents to seek views and support for the use of confidential patient information for the Health & Wellbeing Survey 2022. This exercise was conducted with the support of colleagues in Healthwatch and Warrington Voluntary Action (WVA) and a total of 115 residents completed the consultation. The feedback has been provided for CAG review. Support appears to be in place for this use of confidential patient information without consent. The Members were content with this response.

6. **Provide a copy of the final 2022 health and wellbeing survey for information purposes following the completion of patient and public engagement and planning.**

The CAG were content with the survey information provided.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **21/22** DSPT reviews for **NHS Digital, Direct Data Analysis, and Central Mailing Services** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker

d. 22/CAG/0128 - Stroke Patient Reported Experience Measures (PREMS) Survey 2022

Name	
Dr Harvey Marcovitch	CAG member
Ms Diana Robbins	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Mr Will Lyse	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application submitted by The Stroke Association, as joint data controllers with NHS England, sets out the purpose of conducting the 2022 Stroke Patient Reported Experience Measures (PREMS) Survey.

The purpose of the Stroke PREMS survey is to undertake a national survey which captures the patient experience of stroke care, and to use the survey findings to inform quality improvement activity at local, regional, and national level – in line with the NHS's statutory responsibility for quality improvement. No such patient experience tool or data exists at a national level, and yet this is part of the Stroke Long Term Plan ambitions for England. The survey will support nationally recognised aims of:

- Improving the quality and standard of stroke care and rehabilitation across England.
- Supporting a shift in focus towards measuring patient reported experience measures.
- Placing the experience of people affected by Stroke at the heart of Stroke services.
- Ensuring that Stroke patient experience measurement becomes a regular feature and key driver for improving and learning from patients to improve the services experienced by them.

There are approximately 80,000 strokes per year. Some patients will require inpatient stroke rehabilitation, but for the majority of patients, rehabilitation will take place in the community. The intention is to use the patient-reported data to better understand patients experiences across the entire stroke pathway, from emergency admissions, acute stroke unit stay, community or inpatient rehabilitation and life after stroke

services. The outcome aims to enable further improvements to improve the experience, and hopefully outcomes, for stroke survivors.

's251' support is requested to allow Trusts to disclose confidential patient information to Quality Health for the purposes of undertaking a postal questionnaire survey. Quality Health will contact patients by post. Patients will be sent a survey pack initially. This will include the survey itself, cover letter and language leaflet. A first reminder will be sent 5 weeks after the survey to non-responders only. A second reminder and another copy of the survey will be sent 4 weeks later to non-responders only. If patients opt-out of the survey they will not receive further letters or communication. Questionnaires are sent back to Quality Health, and this is taken as implied consent to take part. Quality Health undertake analyses, and provide anonymous outputs to the Stroke Association.

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

Confidential patient information requested

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

Cohort	Adult stroke survivors (aged 18+) who have experienced a confirmed Stroke and were admitted to an NHS England stroke service within the last 4-8 months Maximum estimated number of patients contacted; 27,712
Data sources	1. NHS Patient Administration System (PAS) from participating Trusts
Identifiers required for patient	1. NHS number, 2. Name, 3. Address including postcode, 4. Sex, 5. Ethnicity,

invitation purposes	6. Date of birth, 7. ICD10 code, 8. Date of stroke, 9. Specialty code, 10. Treating NHS Trust, 11. NHS Trust of residence or commissioning board.
Identifiers required for analysis purposes	1. Date of birth – modified to age 2. Ethnicity 3. Gender This would be effectively anonymous, and additionally analysis undertaken with consent as the legal basis

Confidentiality Advisory Group advice

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

1. **Please provide the formal letter of support from the Caldicott Guardian equivalent of the submitting organisation.**

The applicant provided this and the CAG were content with the provision.

2. **Ensure the website text is updated for accuracy as per this letter, and provide an updated version back to CAG.**

The applicant provided this and the CAG were content with the updates.

3. **Please ensure the flyer and the poster are updated regarding the inaccurate comment about having previously opted out of national surveys, when this should read national Data opt Out, and provide updated versions back to CAG.**

The applicant provided this and the CAG were content with the updates.

4. **Please ensure the cover letter is updated for accuracy with the points in this letter, and provide an updated version back to CAG.**

The applicant provided this and the CAG were content with the updates.

5. **Please later the front page of the survey to make it clear that NHS England do not hold contact information, and this is only referring to Quality Health, and provide an updated version back to CAG.**

The applicant provided this and the CAG were content with the updates.

6. **Please ensure consistency and clarity in the cover/invitation letter, and any reminder letters regarding the possibility that third parties such as relatives and carers may have opened this letter on the patients behalf, and may have a further role to play, and provide updated versions back to CAG.**

The applicant provided this and the CAG were content with the updates.

7. **Please provide more detail surrounding the patient and public involvement activity surrounding the use of confidential patient informaiton without consent, including who the 21 respondents were to ensure they are representative of the cohort, what was covered, and what were the views on use of confidential patient data without consent.**

The applicant provided a much more detailed description, and the CAG were content with the response.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **21/22** DSPT review for **Quality Health** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 08 September 2022)

e. 22/CAG/0095 - UK Early Life Cohort Feasibility Study

Name	
Dr Patrick Coyle	CAG vice-chair
Mr David Evans	CAG member
Mr Tony Kane	CAG member
Dr Pauline Lyseight-Jones	CAG member
Mr Andrew Melville	CAG member
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Mr Umar Sabat	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from University College London set out the purpose of a feasibility study to provide evidence on the potential for successful recruitment into a new national birth cohort study, and to inform on the best approach of design and measurement.

The Early Life Cohort Feasibility Study (ELC-FS) will test proof of concept for a new national birth cohort study for the UK. It will collect rich data on a new generation of babies, born across the UK in the year 2021, capturing the economic and social environments into which these babies are born, and their health, well-being and development in their first 6 months.

Data collection for the ELC-FS will take place when the baby is around 6 months old. NHS Digital will create a list of eligible patients in England and Wales from Birth Registrations data. This will be disclosed to the fieldwork agency, Ipsos Mori. Ipsos Mori who will send information about the study to selected patients. Their participation will then proceed on a consented basis.

A recommendation for class 2, 3, 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	Approximately 2,500 babies in England and Wales, aged 6-10 months
Data sources	1. Birth Notification data, Birth Registrations data and Patient Demographics Service, NHS Digital

Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Date of death 5. Postcode – unit level 6. Full address
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – unit level 4. Gender 5. Occupation 6. Ethnicity

Confidentiality Advisory Group advice

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

1. **Further justification needs to be provided on why a conditional outcome needs to be in place before the tendering process for the fieldwork agency can begin.**

The applicants provided further details on why the fieldwork agency could not be identified until a conditional recommendation of support was in place. On reviewing this information, the CAG determined that the fieldwork agency needed to be identified, so that support could be given for the specific data flows involved.

The applicants then confirmed that Ipsos Mori had been identified as the fieldwork agency. The applicants confirmed that support was required for the below data flow:

- The disclosure of confidential patient information from NHS Digital to Ipsos Mori.
- Ipsos Mori will send the advance booklet and letter to patients identified and eligible to take part. The letter will let people know how to opt out of the study/being recruited to the study.
- Patients participation will then proceed on a consented basis.
- Only confidential patient information for consenting patients will be disclosed to University College London.

The CAG noted this response and raised no further queries in this area.

2. **Provide assurance that the terms and conditions of app usage include the use of data as proposed in the application.**

The applicants explained that the Baby Steps information sheet outlined how the data from the app would be collected and used. In the app store, before installation, there will be a link to the study's Privacy Policy and app privacy information. After the app is installed, in order to use it the parent needs to confirm they have had the opportunity to read the Baby Steps information sheet and to ask any questions and they need to confirm they are happy to take part. There will also be a link to the study's privacy policy prior to the parent signing up to take part.

The CAG noted this response and raised no further queries in this area.

3. **Details need to be provided on how patient notification and communication would be conducted if parents were separated and/or were not in communication with each other.**

The applicants advised that, for parents who were separated, they would contact each parent separately, if the details for both were available on the sampling frame. Addresses and survey responses would not be shared with either parent.

The CAG noted this response and raised no further queries in this area.

4. **Further details on the patient notification and project-specific dissent mechanism need to be provided. This needs to include:**

    a. **Clarification on whether the participants referred to are the parents/carers or the children, so it is clear who the communication materials are targeted to.**

Communication materials are targeted to the parents or caregivers as appropriate of the 6-month-old children. However, participants in the study include both parents or caregivers, and children.

    b. **A clear explanation of how patients can opt-out of the inclusion of their or their child's data in the study needs to be provided.**

The advance letter provides parents with the opportunity to opt out of taking part in the study. Parents need to give their consent for themselves and their child to take part in the study. They can opt out of taking part at any point and that participation in the study is completely voluntary.

For those parents who opt out or do not take part in the study, the information provided in the privacy notice explains the de-identified data that would be held by the study about them, how the data would be used and also how they can opt out of their or their child's data being held and used in this way. There is a link to the privacy notice in the advance letter.

The CAG noted the above responses and raised no further queries in this area.

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 08 April 2022.**

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

   The NHS Digital **2021/22** DSPT reviews for **University College London, Ipsos Mori and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 August 2022).

f. 22/CAG/0088 - Evaluating ICON: A mixed methods study to assess the impact of the ICON programme on coping strategies for carers of crying babies, and rates of abusive head trauma in infants aged under one year.

Name	
Dr Tony Calland MBE	CAG Chair
Professor William Bernal	CAG alternative vice-chair
Dr Sandra Duggan	CAG member
Dr Rachel Knowles	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Ms Diana Robbins	CAG member
Mr Dan Roulstone	CAG member

Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from University Hospitals Bristol and Weston NHS Foundation Trust set out the purpose of medical research to evaluate the effectiveness of the ICON programme in reducing incidence of abusive head trauma (AHT) in young infants.

Abusive Head Trauma (AHT) is an injury to the skull or intracranial contents of an infant or young child due to inflicted blunt impact and/or violent shaking. AHT is the most common abusive injury in young children, and occurs most frequently in children under 12 months of age, with an incidence of 20-24 per 100,000 infants per year in the UK. Alongside the physical and emotional consequences for children and their families, AHT is also associated with large lifetime costs from both healthcare and wider societal perspectives. Societal stressors, which include financial recession or natural disasters, are associated with increased AHT rates. However, the most strongly reported association has been with the peak of normal infant crying, a pattern of rising intensity and duration of crying which peaks at 5-6 weeks of age and subsequently settles in an otherwise well infant. Several programmes providing education and support to families have been designed in an attempt to change infant/caregiver interaction, with the aim of reducing incidences of AHT. Whilst early evaluations demonstrated effectiveness of programmes in reducing rates of AHT, this has not subsequently been replicated. However, studies consistently demonstrate numerous other positive outcomes, including increased knowledge and changed response behaviours to normal infant crying, increased seeking of support, and reductions in Emergency Department attendances.

The ICON programme was developed for implementation in the UK. This programme consisted of four simple messages for parents which highlighted the normality of infant crying, suggested that they attempted to comfort the infant, taking a short time away if frustrated, and to never shake the baby. These messages were reinforced during five key touchpoints with health professionals, including antenatally, after delivery, in the community, and in primary care. Additional innovative and suggested touchpoints include social media, accessing high school children, and at every planned or unplanned contact with healthcare, including Emergency Departments.

The ICON programme has been rolled out to a number of regions since its inception, and a post-implementation evaluation from one of these localities has identified a number of positive impacts. On recognising the likely significant societal stress as a consequence of the COVID-19 pandemic, the ICON programme was implemented by NHS England as a single touchpoint tool across all English maternity units in March 2020. An initial survey-based evaluation of this implementation demonstrated good uptake but also identified a number of challenges, especially in accessing male partners. The applicants seek to build on this and other ongoing work to deliver a mixed methods evaluation study.

Two qualitative studies will be conducted, involving interviews with the parents/carers of children with AHT and interviews with professionals involved in implementing or delivering the ICON messages. These studies are outside the scope of support. Support is needed for a quantitative study. Holders of relevant national datasets, including Hospital Episode Statistics Admitted Patient Care, Emergency Care and Diagnostic Imaging Datasets, the Trauma and Audit Research Network (TARN) dataset, the National Child Mortality Database (NCMD), and the Paediatric Intensive Care Audit Network (PICANet), will identify patients with AHT. Confidential patient information for patients meeting the inclusion criteria will be disclosed to NHS Digital. NHS Digital will undertake linkage and disclose pseudonymised data to the research team at University Hospitals Bristol and Weston NHS Foundation Trust. NHS Digital will retain the linkage key, therefore the pseudonymised data provided to the research team will be effectively anonymised.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Qualitative; parents/carers - (i) male and female carers aged 18 years or older, (ii) received ICON messages at least once

	before the baby was eight weeks old, (iii) timeline from delivery to interview of 2-6 months Qualitative; professionals - those eligible will be responsible for commissioning, implementing, or delivering the ICON messages. Quantitative: patients aged up to 364 days who were diagnosed with AHT between 01 January 2016 and 31 December 2021.
Data sources	1. Hospital Episode Statistics Admitted Patient Care, NHS Digital 2. Emergency Care and Diagnostic Imaging Datasets, NHS England 3. The National Child Mortality Database (NCMD), University of Bristol 4. The Trauma & Audit Research Network (TARN) dataset, Northern Care Alliance NHS Foundation Trust 5. PICANet, Universities of Leeds and Leicester
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – district level 3. Gender 4. Ethnicity

Confidentiality Advisory Group advice

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

1. **Provide details on how the publication of small numbers and risk of re-identification would be handled.**

The applicants acknowledged that statistical data has a residual risk of disclosure. The applicants planned to manage any confidentiality risk from publication of small numbers by following good practice, such as only collecting the data that is sufficient and necessary for the study, suppressing cells in output tables with values of less than 5 cases, collapsing data categories to ensure output tables contain cells with data values fewer than 5 cases and ensuring that accumulating published circumstantial information cannot lead to identification of individual cases. The CAG noted this information and raised no further queries.

2. **The passage on page 4 of the Privacy Notice needs to be revised to make it clear that patients can dissent to use of their information and don't need to wait for the project to be completed before this can be requested.**

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

3. **Provide details about the revisions and additions to notification materials outlined on page 5 above.**

NHS Digital will apply the National Data Opt-Out. This information had been added to the Privacy Notice and information materials. The data that will be received by the research team is anonymised and it will not be possible for the team to remove patients from the research dataset.

The Privacy Notice now includes an introduction to the National Data Opt-Out, the link to respective websites providing information on the National Data Opt-Out including the website where people can indicate they would like to Opt-out from the study, and contact details of the NHS Digital Team.

The applicants are also developing posters, which fill provide information about the study, the use of data in the study, and how they can request for their data to be removed for use in the study (the National Data Opt-Out). The posters will be presented to and refined with help from our PPI contributors.

The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 06 July 2022.**

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

   The NHS Digital **2020/21** DSPT reviews for **NHS Digital, NHS England, the National Child Mortality Database (University of Bristol), TARN (Northern Care Alliance NHS Foundation Trust) and PICANet (Universities of Leeds and Leicester)** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20 June 2022).

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

Name	
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Dr Patrick Coyle	CAG vice-chair
Mr David Evans	CAG member
Professor Lorna Fraser	CAG member
Dr Harvey Marcovitch	CAG member
Ms Diana Robbins	CAG member
Mr Umar Sabat	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr Will Lyse	HRA Approvals Administrator

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research that seeks to explore how the new NHS-funded tobacco dependence services are delivered in acute hospital, mental health inpatient and maternity settings, and the service's impact on health and care.

NHS-funded tobacco dependence services are delivered in England as part of the NHS Long Term Plan. The applicants seek to evaluate how these services are delivered in five geographical regions, the North-East and North Cumbria, Greater Manchester, Yorkshire and Humber, West and West Midlands.

The applicants will survey NHS staff and service users. Hospital records will be accessed to determine the number of smokers who have been offered and used the service and to calculate the cost of providing the service. Support is required for Work Packages B and C, where confidential patient information will be extracted from patient records by members of the direct care team and by members of the research team. The dataset will be transferred to Newcastle University and the pseudonymisation key held

by the participating trusts, making the dataset at Newcastle University effectively anonymised.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over who: • Identified as smokers aged 18 years or over where length of stay in acute settings is greater than one day • Identified as smokers accessing maternity services • Identified as smokers accessing mental health (inpatient) services The applicants estimate that around 180,000 patients will be included under support.
Data sources	1. Electronic patient records at: • Manchester University NHS Foundation Trust • Gateshead Health NHS Foundation Trust • Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust • Northumbria Healthcare NHS Foundation Trust • South Tyneside and Sunderland NHS Foundation Trust • Tees, Esk and Wear Valleys NHS Foundation Trust • Sandwell and West Birmingham Hospitals NHS Trust

	• Gloucestershire Hospitals NHS Foundation Trust • The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS Number 2. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level 2. Gender 3. Ethnicity 4. Age

Confidentiality Advisory Group advice

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

1. **Provide further details on how the aggregate data would be used to provide information for the health economics aspect of the study.**

The applicants explained that the purpose of the health economic analysis is to estimate the cost-effectiveness of the service. The aggregate data for quit rates will be used as the main outcome measure in the economic analysis.

The aggregate data regarding service delivery, uptake and post-discharge smoking metrics will also be used to estimate the cost of implementing the intervention. If available for analysis, the aggregate HES data will be used to estimate the health care costs (from admissions, A&E attendances and outpatient appointments) for the smokers who undertook an intervention. The CAG noted this information and raised no further queries.

2. **Provide clarification on who will undertake the data extraction, members of the research team or members of the direct care team.**

The applicants clarified that the data extraction will not be undertaken by either the research team or members of the direct care team. Instead, data extraction will be delegated to the data teams within each participating NHS Trust. The CAG noted this information and raised no further queries.

3. **Provide clarification on whether the data linkages referred to in the application are linkages to data held within the participating trusts or if any linkages to other datasets, such as HES patient-level data, are planned.**

The applicants clarified that no data linkages will be conducted to data held by participating trusts or patient level data held by NHS Digital. The CAG noted this information and raised no further queries.

4. **If patient identifiers are only needed to collect follow-up data, please advise whether other ways of conducting the data linkages could be implemented, such as application of a study ID number.**

The applicants advised that use of a study number would be introduced. The CAG noted this information and raised no further queries.

5. **Further justification needs to be given on why the research team require access to confidential patient information and why anonymised data only cannot be used.**

The applicants explained that pseudonymised data was required to ensure consistency in the data coding, management, cleaning and analysis. A fully anonymised dataset would mean that certain analyses could not be undertaken. The CAG noted this information and raised no further queries.

6. **Advise whether the postcodes can be converted to Lower Super Output Area (LSOA), and then the full postcodes deleted.**

Full postcodes will be converted to LOSA after transfer to Newcastle University. The full postcodes can then be deleted. The CAG noted this information and raised no further queries.

7. **Confirm that the National Data Opt-Out will be applied.**

The applicants confirmed that the National Data Opt-Out will be applied. That had been added to the study poster and website information. The CAG noted this information and raised no further queries.

8. **Further methods of patient notification also need to be considered, such as adopting a layered approach, making information available online as well as leaflets and posters. A communications plan and any additional documents are to be provided to the CAG for review. The National Data Opt-Out also needs to be explained on the patient notification materials.**

The applicants advised that the poster had been updated to refer to the National Data Opt-Out. A page had also been added to the project website to provide in-depth information about the project.

The CAG reviewed the information provided and was largely satisfied with the documents. However, members noted that the role of the CAG had not been correctly described in the website information. Members suggested that the following text was used:

The application was reviewed by the Confidentiality Advisory Group (CAG). They are an independent group of lay people and professionals which provides expert advice on the use of confidential patient information without consent. CAG recommended that our application should be supported and the Secretary of State for Health approved this.

9. **Further patient and public involvement needs to be conducted with a larger group. This further activity needs to include a review of the patient notification materials and the asking of an open question on the use of confidential patient information without consent.**

The applicants provided information on further patient and public involvement that had been conducted. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. The website information regarding the role of the CAG needed to be revised, in line with the suggested text above.

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

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

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

2. New Amendments

21/CAG/0155 – Using patient records to identify potential participants for the fourth National Survey of Sexual Attitudes and Lifestyles (Natsal-4)

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

Context

Amendment request

The applicants have existing support to allow NHS Digital to identify a sample of eligible English patients from the Demographics service and Hospital Episode Statistics (HES), and for Digital Health and Care Wales (DHCW) to identify a sample of eligible Welsh patients from the Welsh Demographics dataset, and to allow the disclosure of confidential patient information from NHS Digital to NatCen. NatCen will then send the mail merge files to Formara, a sub-processor who will carry out print and dispatch, in order for Formara to send out invitation letters to eligible patients, and to allow onwards disclosure of confidential patient information to interviewers. NatCen will also send confidential patient information to interviewers' electronic devices and Formara will send confidential patient information (paper address forms) to NatCen interviewers home addresses. The support also extends to allowing record-level fieldwork recruitment outcomes containing confidential patient information to be transferred back from interviewers' devices to NatCen.

The application also has an option to use an 'address-based sample' approach, where addresses are selected from the Postcode Address File (PAF). This has previously been approved by the REC and does not require CAG support since it does not involve processing confidential patient information.

This amendment seeks 's251' support for introducing a 3rd option for sending invitations out – using an 'enhanced address-based sample', which combines the PAF option, which doesn't ordinarily require CAG support, with the use of minimal identifiers to see if any individuals are eligible before the letters are sent, which is the element requiring 's251' support. The applicant wishes to use all 3 potential options as recruitment methods, as there are delays with the original CAG supported option.

For this methodology, applicants estimate that they will need to send the Data Controllers a selected sample of approximately 28,000 addresses for the core sample,

81,000 addresses for the young person boost sample and 250,000 addresses for the ethnic minority boost sample. NHS Digital will use the addresses to link to the Demographics service and HES, and DHCW will use the addresses to link to the Welsh Demographics data, using date of birth, ethnicity and gender to help establish eligibility. This does require 's251' support. NHS Digital, and DHCW will disclose a list of linked addresses, date of birth, ethnicity and gender to Natcen, which also required 's251' support. Natcen will screen out those who are ineligible and delete that data. Addresses which are unclear if eligible, or those that are eligible, are then processed in the same way as the PAF sampling, and the data supplied by NHS Digital is removed. Letters are sent out to addresses in the same manner as the usual PAF sample approach. The applicant has also supplied an updated flowchart and associated documentation.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The CAG Alternative-Vice Chair agreed that the amendment was in the public interest.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **2021/22** DSPT reviews for **NatCen Social Research, Formara Limited and NHS Digital** were confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 08 September 2022).

   A C-PiP report for DHCW is in place.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non-notifiable 26 August 2022.**

21/CAG/0117 – CCP-Cancer UK: Clinical Characterisation Protocol for Severe Emerging Infections in the UK (CCP-UK) – a prospective companion study for patients with Cancer and COVID-19.

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

Context

Amendment request

This application from University of Liverpool seeks to determine the Covid-19 fatality rate within the cancer population and to identify factors associated with poor outcomes from Covid-19 in patients with cancer. 's251' support is currently in place to allow the disclosure of confidential patient information from the ISARIC CCP-UK study at the University of Oxford to the University of Edinburgh, and the onward disclosure of confidential patient information to the NCRAS dataset at Public Health England (now at NHS Digital) for data linkage, and the return of a pseudonymised dataset to the PHS Scottish National Safe Haven. 's251' is also in place to allow confidential patient information from the ISARIC CCP-UK study to be disclosed from the University of Edinburgh to the University of Liverpool, where local research teams will access the REDCap database to populate the records of eligible patients. The University of Liverpool will then pseudonymise the data and send a pseudonymised dataset to the PHS Scottish National Safe Haven.

This amendment sought support to include a similar process to that already in place for England and Scotland, for linkage with Welsh outcome data. The applicant proposes to disclose confidential patient information regarding approximately 500 patients to Digital Health and Care Wales via the Secure anonymised data linkage (SAIL) Databank. These 500 patients are Welsh patients and their cancer data will be linked to their other healthcare data within SAIL and analysed to provide outcomes on the impact, treatment, plus future management of Welsh patients with cancer who also contracted COVID-19.

This amendment also sought to clarify that the 'conservative estimate of 5000...' patients recruited within a stipulated period was definitively 5000 patients.

This amendment also sought to clarify that the 5000 patient records were accessible from a single transfer of identifiers provided by The University of Edinburgh, rather than the original perception of numerous transfers being required.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action, who was supportive of this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **21/22** DSPT reviews for **SAIL Databank and SeRP UK (within Swansea University), University of Oxford, and University of Liverpool** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 September 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 10 August 2022**

22/CAG/0003 – Emergency Medical Services Streaming Enabled Evaluation In Trauma

Name	Capacity

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

Context

Amendment request

This application from the University of Surrey aims to explore the feasibility of conducting a future randomised controlled trial to assess the clinical and cost effectiveness of using GoodSAM live video streaming to improve targeting of emergency medical resources.

Applicants have 's251' for various elements of the study, but relevant to this amendment, 's251' support is in place for the collection of CAD (computer aided dispatch) number, estimated age and estimated sex, and brief details of the type of trauma incident/type of injuries, regarding individuals (casualties) involved in the trauma incidents included in the trial, by the research paramedic, and for the Trusts to use the CAD number to locate surviving casualties and seek consent or a consultee opinion once they are admitted to a participating hospital.

In the original application, the applicant explained that patient names are not always recorded in trauma incidents in the pre-hospital setting, so the researchers may not have access to their names until they are in hospital. The CAD (computer aided dispatch) number is the ID that would link the incident to the patient. At the time, '*The CAG noted that the full names of the patients would not be collected… noting that they would be in favour of this being collected if needed'*

This amendment is to include name in the data items collected by the Research paramedic at the time of the incident (if available), and provide names to the hospitals with the other data they are collecting to try to improve the hospital's ability to identify (and thereby approach for consent) casualties involved in incidents in this study. The patients' name is not required for any other purpose and would not be included in the study database transferred to University of Surrey. This amendment only relates to data collected within the South East Coast Ambulance Service NHS Foundation Trust.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team, As the CAG had indicated in the original outcome letter that they were supportive of the collection of name.

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.

Exceptionally, this amendment is supported prior to the NHS Digital DSPT review for **London Ambulance Service NHS Trust,** as the amendment does not relate to this Trust, and the addition of name will enable more individuals to be consented and exit from 's251' support. The applicant is to provide the DSPT review once available and a final outcome letter will be issued.

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **21/22** DSPT review for **the South East Coast Ambulance Service NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 22 September 2022)

   Pending: The NHS Digital **21/22** DSPT review for **London Ambulance Service NHS Trust** is currently pending, however as this amendment relates only to SECAMb, the amendment can be exceptionally supported.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 12 September 2022**

CAG 7-04(a)/2013 - Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors working on behalf of GPs

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

Context

Amendment request

The current application has relied on Regulation 5 support since January 2014 to provide a legal basis for GP data and secondary care data (from NHS Digital) to be linked by "approved organisations". Doing so enables GPs to identify at risk patients and allows for targeted interventions to be made as early as possible (risk stratification). NHS England manages the application on behalf of GPs/Integrated Care Boards (ICBs), who are the data controllers.

This amendment is to extend the duration of support for a further 12 months, whilst a revised framework submission is prepared.

Confidentiality Advisory Group advice

The amendment requested was considered by the CAG Officers. CAG officers noted the previous CAG condition of continued support in the annual review outcome letter dated 19 May 2022 that requested a new application submitted to CAG by 30 September 2022.

Following this, the CAG chair met with representatives from NHS England and the NHS Transformation Directorate to agree a pragmatic way forward for management and oversight of risk stratification. NHS England explained the difficulties in reaching this deadline because of the recent establishment of Integrated Care Boards (ICBs), replacing Clinical Commissioning Groups (CCGs). Whilst ICBs are now legal entities each are at various stages of maturity which impacts on the ability to coordinate a refreshed application with the necessary detail. In addition, the upcoming changes

with NHS Digital moving to NHS England has the potential to impact on the risk stratification activities.

As such, the CAG agreed to a twelve-month extension of the current risk stratification application to enable a fully refreshed framework application to be submitted. As part of the framework application CAG expects the specific areas raised in the 19 May 2022 annual review outcome letter to be taken into account.

NHS England also committed to understanding for what other purposes ICBs may be using risk stratification data or additional dataflows, that are outside the scope of the current risk stratification support. This is with the view to agree steps to ensure an appropriate common law legal basis is in place for these activities.

It was agreed that CAG will hold bimonthly meetings with NHS England to review progress toward a new application.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Support is extended until 30 September 2023

2. A new framework application is submitted prior to this date to ensure support is continued post 30 September 2023

3. Bimonthly meetings are held with CAG during this period to review progress towards a new application

4. All other conditions applied as part of the annual review outcome letter (letter dated 19 May 2022) remain.

CAG 7-07(a)/2013 - Application for transfer of data from the HSCIC to commissioning organisation accredited safe heavens: inclusion of invoice validation as a purpose within CAG 2-03 (a)/2013

CAG 7-07(b)/2013 - Invoice validation within Clinical Commissioning Groups (CCGs) Controlled Environment for Finance (CEfF)

CAG 7-07(c)/2013 - Invoice validation within NHS England within the Commissioning Support Units Controlled Environment (for Finance) (CEfF) on behalf of Clinical Commissioning Groups

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

Context

Amendment request

In this amendment, the applicants requested an extension to the duration of support to continue the legal basis permitting Integrated Care Boards (ICBs) and Commissioning Support Units (CSUs) to process confidential patient information under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 for invoice validation purposes. Support is currently in place until 30 September 2022 and the applicants sought to extend this by a further 12 months until 30 September 2023.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair and Confidentiality Advice Team. The amendment set out that the extension would allow a continuation in ensuring that organisations receive the correct funding for the NHS services they provide which is essential to maintain the NHS. The request stated that extending

support would maintain essential business continuity and healthcare services to patients. Invoice validation is part of the effective management of health and social care services, ensuring that providers are appropriately reimbursed for the care and treatment they deliver to patients. The process confirms that providers receive the correct amounts by checking that the correct patient received the correct treatment and that the correct commissioner has been identified. Invoice validation allows prompt payments to healthcare providers to be made and fulfils the commissioners' duties for fiscal probity and scrutiny.

The CAG advised that the importance of continuing support would provide a clear public benefit in terms of the management of health and care services.

Security assurances

It is the policy position of the Department of Health and Social Care (DHSC) in England that all approved activities seeking support to process confidential patient information without consent must evidence satisfactory security assurances through completion and satisfactory review by NHS Digital of the relevant Data Security and Protection Toolkit (DSPT). In England, security is considered satisfactory once NHS Digital confirm (via internal tracker or direct email) that the relevant entity has achieved 'standards met' or 'standards met – improvement plan in place'. This process applies to all supported activities.

Following review of the information submitted in the amendment, at time of submission, and following recent review of NHS Digital's internal tracker, there are two entities that have not achieved the appropriate level of security assurances necessary to process confidential patient information under support. These are:

1. NHS South, Central and West CSU
2. NHS Midlands and Lancashire CSU

It is important to recognise that those entities that do not meet the standard security assurance level are not covered by the legal support as the conditions of support are not being met.

The CAG understands the importance of the activity proceeding, however noted that it is important for public confidence that those operating under support maintain an appropriate level of security assurance in line with all other supported application activities.

CAG advised that, on an exceptional basis, a clear update should be provided within one month of date of this letter. In the first instance please follow steps 1-4 as outlined here to provide CAG confirmation of NHS Digital assurances of the satisfactory DSPT review of the above organisation.

Annual review Conditions

It is noted that the previous annual review requested a timeline for submission of a new application. It is expected during the course of the next year a timescale for a new submission is agreed with CAG.

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 to extend the duration for a further 12 months.

Specific conditions of support

The following sets out the specific conditions of support.

1. Provide confirmation of NHS Digital DSPT assurances for NHS South, Central and West CSU and NHS Midlands and Lancashire CSU within one month.

2. Agree timescale with CAG for a resubmission of the invoice validation application

22/CAG/0006 – Developing a digital handover application for paramedics to provide a personalized approach to pre-hospital stratification for OOHCA – the RAPID-MIRACLE study

Name	Capacity
Ms Katy Cassidy	HRA Confidentiality Advsor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from the London Ambulance Service to King's College Hospital NHS Foundation Trust, and then to the treating hospital trust so that the investigator at this site can complete the eCRF, and the return of a pseudonymised dataset to King's College Hospital NHS Foundation Trust.

The applicants seek to include West Hertfordshire Hospitals NHS Trust, Barking, Havering and Redbridge University Hospitals NHS Trust, The Hillingdon Hospitals NHS Foundation Trust, London North West University Healthcare NHS Trust (LNWH), North Middlesex University Hospital NHS Trust, University College London Hospitals NHS Foundation Trust, Whittington Health NHS Trust and Surrey and Sussex Healthcare NHS Trust. These trusts were to be included in the original application, but an out of date list of participating trusts was provided.

The applicants also noted that the data flow had been revised, so that the London Ambulance Service will contact the teams at participating sites directly to check patient status and to arrange the consent visit. This change has been made so that staff at King's College Hospital will not have access to confidential patient information for patients who have died or dissented to inclusion. The applicants also confirmed that consultees would not be approached for patients who lacked capacity. For patients who died before consent could be sought, the National Data Opt-Out would be applied. For surviving patients, they will be enrolled onto the study under the emergency research provisions of the Mental Capacity Act and, once they regain capacity, will be informed of their enrolment into the research and given the opportunity to dissent.

The applicants also sought to revise the end date of the study. The projected end date is now 07 September 2024.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. The CAT agreed that the changes made were in the public interest.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 02 March 2022** (the REC outcome correctly included Lewisham and Greenwich NHS Trust).

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

The NHS Digital **2021/22** DSPT review for **the below organisations** were **confirmed** as 'Standards Met' on the NHS Digital DSPT Tracker (15 August 2022):

- Barts Health NHS Trust
- Central and Northwest London NHS Foundation Trust
- Chelsea and Westminster Hospital NHS Foundation Trust
- Croydon Health Services NHS Trust
- Dartford and Gravesham NHS Trust
- Epsom and St Helier University Hospitals NHS Foundation Trust
- Guy's and St Thomas' NHS Foundation Trust (includes Royal Brompton and Harefield NHS Foundation Trust)
- Homerton University Hospital NHS Foundation Trust
- Imperial College Healthcare NHS Trust
- King's College Hospital NHS Foundation Trust

- Kingston Hospital NHS Foundation Trust
- Lewisham and Greenwich NHS Trust
- London Ambulance Service NHS Trust
- Royal Free London NHS Foundation Trust
- St George's University Hospital NHS Foundation Trust
- Barking, Havering and Redbridge University Hospitals NHS Trust
- The Hillingdon Hospitals NHS Foundation Trust
- London North West University Healthcare NHS Trust (LNWH)
- North Middlesex University Hospital NHS Trust
- Surrey and Sussex Healthcare NHS Trust
- University College London Hospitals NHS Foundation Trust
- West Hertfordshire Hospitals NHS Trust
- University College London Hospitals NHS Foundation Trust
- Whittington Health NHS Trust

22/CAG/0107 – The 2022 Urgent and Emergency Care Survey

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application is to allow the disclosure of confidential patient information from NHS trusts to one of three approved contractors for the purpose of sending out questionnaires for the 2022 Urgent and Emergency Care Survey, and for disclosure of postcode to the Survey Coordination Centre for Existing Methods (SCCEM) at Picker for analysis purposes.

's251' support is currently in place for the following sample sizes;

- Trusts with only Type 1 departments, the sample size is 1250 patients.
- Trusts who have both Type 1 and Type 3 departments will submit a sample size of 950 Type 1 patients and 420 Type 3 patients, a total of 1370 patients.

This amendment sought support for an increase in sample size to the following;

- For trusts with only Type 1 departments, the sample size will remain at 1250 patients.
- Trusts who have both Type 1 and Type 3 departments will submit a sample size of 950 Type 1 patients (no change) and 580 Type 3 patients, a total of 1530 patients.

This is due to a recent decline in responses to the survey.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. No queries were raised regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the 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 IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **21/22** DSPT reviews for **Patient Perspective Ltd, Picker Institute Europe and Quality Health Ltd** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 September 2022)

3. Annual Review Approvals

18/CAG/0040	eLIXIR, Early Life course data Cross-LInkage in Research
19/CAG/0136	Acute Leukemia in Pregnancy Registry Study
20/CAG/0110	Understanding the epidemiology in the transition from neonatal to paediatric care: a data linkage
19/CAG/0035	Updating cancer survival index trends for England and Wales to 2018
18/CAG/0153	The POOL study: Establishing the safety of waterbirth for mothers and babies: A cohort study with nested qualitative component.
ECC 3-04(i)/2011	Global surveillance of cancer survival (CONCORD programme)
15/CAG/0175	Early life causes of depression and anxiety
18/CAG/0091	Connected Bradford - Linked Education and Health Research Database
19/CAG/0053	Myeloproliferative neoplasms Associated Splanchnic vein thrombosis: Mascot registry
19/CAG/0054	An evaluation of knee arthroplasty fixation in an evolving challenging population
ECC 3-03(c)/2012	Manchester Cancer Research Centre Biobank - collection of tissue, blood and urine for cancer research
ECC 5-02(FT4)/2009	Study of Heart and Renal Protection (SHARP)
16/CAG/0079	National Clinical Audit of Breast Cancer in Older Patients (NABCOP)
17/CAG/0076	The Invasive Dentistry – Endocarditis Association (IDEA) Study: A Study of the link between invasive dental procedures and critical medical events including infective endocarditis, myocardial infarction, stroke, pulmonary embolus and spontaneous pre-term birth.
17/CAG/0058	National Chronic Kidney Disease Audit

21/CAG/0136	National Drug & Alcohol Treatment Monitoring System (NDTMS) & Criminal Justice Intervention Teams (CJIT)
CAG 8-03(PR11)/2013	Hip Fracture Audit
19/CAG/0215	Fractional Flow Reserve versus Angiographically Guided Management to Optimise Outcomes in Unstable Coronary syndromes: a developmental clinical study of management guided by coronary angiography combined with fractional flow reserve (FFR) measurement versus management guided by coronary angiography alone (standard care) in patients with non-ST elevation MI
21/CAG/0022	The use of telephone based digital triage in urgent care provision and the associated patient service use and health outcomes: A routine data analysis study before and during the Covid-19 pandemic
21/CAG/0033	Risk of Aneurysm Rupture Study (ROAR

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Dr Murat Soncul & Professor William Bernal, CAG Alternate Vice-Chairs	*03 November 2022*
Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*28 October 2022*