Health Research Authority

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

May 2022

1. New Applications

a. 21/CAG/0094

Name	
Dr Patrick Coyle	CAG vice-chair
Professor Barry Evans	CAG member
Mr. Myer Glickman OBE	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This non-research application from East Anglian Air Ambulance (EAAA) sets out the medical purpose which aims to link routinely collected clinical data regarding patients treated by East Anglian Air Ambulance to hospital held NHS data to audit and evaluate the care provided by the air ambulance in relation to the complete patient pathway and patient outcomes. This application is for support to link information regarding the 2020 cohort of patients, and an amendment will be submitted should the applicant wish to undertake linkages of further cohorts.

East Anglian Air Ambulance are a key provider of pre-hospital emergency care within East Anglia, attending the most critically ill patients within the region. Alongside regular audit that is undertaken using in house data, this application requests to link this with centrally held NHS data to audit and evaluate the care provided by the air ambulance in relation to the complete patient pathway and patient outcomes. This gives opportunity for improved clinical excellence, gives learning opportunity for clinical staff and, ultimately, can lead to improved care for future patients (members of the public) of the air ambulance. The intention is to also share outcomes with other air ambulances and NHS partners, so that this project can potentially be of wider regional and national benefit in terms of using data to maximise patient benefit.

Some examples of expected outcomes:

- Accuracy of Dispatch and of Diagnosis: To identify the proportion of patients whose condition is correctly categorised: 1) At tasking 2) At scene based on working diagnosis.
- Survival: Proportion of people who survive to discharge.
- Decision making: To consider accuracy of conveyance (e.g. where patients are soon transferred onwards to another hospital) or unnecessary conveyance (patients who had no additional investigations or treatments at hospital which need to be provided in a hospital setting)
- Special cases or rarer conditions - analysis of patient record to look at the whole patient pathway and consider any learning opportunities.
- Impact of pre-existing comorbidities on pre-hospital care. These are recorded as associated diagnoses on the hospital record, but are often not well known about or not recorded during emergency care.

EAAA will provide NHS Digital with identifiers of eligible patients. Whilst these may be more than usual these are the minimum necessary to ensure linkage given the EAAA do not record NHS numbers as standard practice. This has been discussed and agreed with NHS Digital. NHS Digital will link to the requested datasets and return the data in pseudonymised form, where it will be linked to currently held clinical data for the purposes described.

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

Confidential patient information requested

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

Cohort	All patients treated by East Anglian Air Ambulance, (excluding those who die before admission to hospital) in 2020.

	These patients are either taken by air ambulance to hospital, 'ground escorted' by EAAA to hospital, whereby EAAA crew accompanies the patient in a road ambulance, or treated by EAAA at scene and then taken to hospital by road ambulance with the normal ambulance crew. This initial phase will test linkage on the 2020 cohort (1384 patients) to test feasibility and usage of date before expanding to further years of data collection, however amendments will be submitted to CAG for support for further cohorts.
Data sources	NHS Digital datasets 1. Hospital Episode Statistics (HES): Admitted patient care 2. Hospital Episode Statistics (HES): Critical care 3. Emergency care data set (ECDS)
Identifiers required for linkage purposes	1. Full name (first name and surname) 2. Date of birth 3. NHS number 4. Age 5. Home address, including postcode 6. Gender 7. Date of admission 8. Hospital of admission
Identifiers required for analysis purposes	1. None
Additional information	Note that the data will be linked to EAAA data through a code, but EAAA will not attempt to reidentify patients through this.

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 website text should be improved by including sufficient details of the study methods, linkage, and local opt-out details, and provided back to CAG for review**

The applicant provided an updated version of the text for the website, and the CAG were content with the information provided.

2. **Please carry out patient and public involvement activities surrounding the acceptability of confidential patient information without consent for the purposes of the application and provide feedback to the CAG.**

The applicants undertook a session with a newly put together patient forum. The applicant provided a summary of the session, including evidence that patient representatives were supportive of the use of confidential patient information for this purpose. The CAG were content with this response.

3. **Please anonymise the dataset by removing the pseudonymous ID or provide sufficient explanation of why that would not be possible and provide an alternative exit strategy.**

The applicant confirmed they will remove the pseudonymous ID from the database, so the data will not be linkable back to the retained patient records and re-identification will not be possible. The data will be stored securely as outlined in the original application. The CAG were content with this response.

4. **Please provide evidence of NHS Digital review of the DSPT for East Anglian Air Ambulance (as per standard conditions of support below).**

This review was completed in July 2021.

Amendment to support

As part of the response to provisional outcome, the applicant sought to amend their ‘s251’ support to include NHS number, (where available) to the patient database, as an identifier required for linkage. They reason that this will improve the quality and accuracy of the linkage and mean that we are less dependent on using names. The CAG were content with this addition, and this has been included in the table above.

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 **20/21** DSPT reviews for **NHS Digital and East Anglian Air Ambulance** are confirmed as '**standards met'** on the NHS Digital DSPT Tracker (Checked 03 May 2022).

b. 22/CAG/0036 - Cardiovascular morbidity and mortality in Liothyronine-treated patients: a linked record cohort study

Name	
Dr Murat Soncul	CAG Alternate Vice Chair
Mr David Evans	CAG Member
Professor Lorna Fraser	CAG Member
Dr Katie Harron	CAG Member
Dr Sandra Duggan	CAG Member

Context

Purpose of application

This application from Cardiff University set out the purpose of medical research that seeks to determine whether patients treated with T3 (liothyronine) have a higher risk of death than those treated with T4 (levothyroxine).

Hypothyroidism or thyroid hormone deficiency affects 1-2 million people in the UK and untreated patients suffer significant ill-health. Levothyroxine (T4) is the conventional treatment for hypothyroidism and most patients who are treated with T4 respond well to treatment and enjoy a good quality of life. However, a small proportion of patients remain unwell with T4 and therefore some practitioners treat such patients with an alternative form of treatment called T3. Although many patients who receive T3 report significant improvement in well-being, the long-term safety of the drug has not been established and current UK and international guidelines do not recommend its routine use in practice.

The applicants seek support to use data collected for patients treated with T3 in an independent medical clinic between 1996 to 2013 in order to evaluate the long-term risk of death, heart disease and strokes. This data is held by the Vaccine Research Trust. The clinic dataset contains data for over 4000 patients. This data will be compared with data for patients treated conventionally for hypothyroidism with T4 and a control group of patients without hypothyroidism. The clinic data will be linked to NHS hospital admission and mortality records via NHS Digital and the Wales Secure Anonymised Information Linkage (SAIL) Databank. Administrators of the Vaccine Research Trust will identify eligible patients through a review of electronic clinic records held by the Trust. Patients treated with T3 will be identified and their demographic clinical and treatment details will be forwarded to NHS Digital and SAIL using a split-file approach in which patient identifiable data (NHS number, gender, date of birth) is sent to NHS Digital and clinical and treatment data is sent to SAIL. A final file comprising pseudonymised linked data with a new encrypted ID for the data groups (T3, T4 and controls) will be made available to Cardiff University researchers via the SAIL portal.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over who were treated with T3 for at least 3 months at an independent medical clinic between 01 January 1996 to 31 December 2013 3100 - patients treated with T3. 3100 - patients treated with T4. 24800 – control subjects, with no thyroid disease Patients in the control group will also have received treatment between 01 January 1996 to 31 December 2013, and will be age and sex matched to the T3 and T4 cohorts.
Data sources	1. Electronic patient records held by the Vaccine Research Trust 2. HES and ONS data, held by NHS Digital 3. Patient Episode Database for Wales (PEDW), ONS, and the Primary Care GP dataset, held by SAIL
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth
Identifiers required for analysis purposes	1. Gender
Additional information	The applicants advised that they would request the week of birth and week of death from SAIL. These will then be truncated to age of death once the survival calculation was completed.

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.

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Confirm that, once the current research project has concluded, the dataset will either be anonymised (i.e. all items of confidential patient information deleted) or another, more suitable, data custodian needed to be identified and ownership of the dataset transferred.**

The applicants confirmed that once the research project is concluded the dataset will be anonymised and all confidential patient information will be deleted and safely destroyed. Linked pseudonymised data held in NHS Digital and SAIL will be retained for a period of 5 years after the study ends. The CAG reviewed this information and raised no further queries. The CAG reviewed this response and raised no further queries.

2. **The *Patient opt out information version 2.5 31st January 2022* document needs to be revised as follows:**

    a. **The project-specific dissent mechanism needs to be displayed more prominently that the National Data Opt-Out.**

    b. **The document needs to be renamed to make it clear that the document relates to the Thyroid T3 study.**

The applicants provided a revised Patient opt out information document. The project specific dissent mechanism was displayed more prominently. Bulleted lists had also been included, which highlighted the contact details for the Vaccine Research Trust. The document had also been renamed to the Thyroid T3 safety study and this name will appear on website links to the document. The CAG reviewed this response and raised no further queries.

3. **Further ways of publicising the study are to be explored.**

The study will be publicised on the websites of the Vaccine Research Trust, the British Thyroid Foundation (BTF), and Thyroid UK (TUK). BTF and TUK are the top patient support groups for individuals with thyroid disease. The study will also be publicised

on the websites of additional support groups, namely the Thyroid Patient Advocacy, The Thyroid Trust, as well as websites of the main thyroid related professional bodies in the UK, namely the British Thyroid Association and the Society for Endocrinology. The CAG reviewed this response and raised no further queries.

4. **Clarify whether patients dates of death will be retained in the linked dataset, or if this data item could be converted to age at death or other alternative.**

The applicants explained that dates of death are needed for the survival analyses, but the actual date of death is not necessary for this analysis. The applicants will therefore use the month of death instead of the exact date of death. The CAG reviewed this response 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 03 April 2020.**

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 **Cardiff University, the Vaccine Research Trust, SAIL (Swansea University) and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 March 2022).

c. 22/CAG/0032 - A Foucauldian discourse analysis of clinicians' language regarding standards of care in the current socio-political NHS context

Name	
Dr Murat Soncul	CAG Alternate Vice Chair
Dr Harvey Marcovitch	CAG Member
Dr Katie Harron	CAG Member
Mr David Evans	CAG Member
Professor Sara Randall	CAG Member

Context

Purpose of application

This application from Surrey and Borders Partnership NHS Foundation Trust set out the purpose of medical research that seeks to investigate the discourses that clinicians draw upon in relation to standards of care when speaking in routine NHS meetings and the implications of the different discourses used.

Research suggests that clinicians working in the NHS experience high pressures to meet service targets and provide 'cost-effective' treatment. Paradoxically, meeting these targets can sometimes feel in conflict with clinicians' person-centred values. Broader issues such as political climate and the government's management of the NHS may play a role in shaping these pressures. However, research exploring these broader issues appears to be absent. The applicants seek to explore how clinicians talk in routine meetings, and specifically, how they may refer to standards of care within the current NHS context. This will require collecting and analysing conversations from various organisational meetings to highlight different ways of talking clinicians may use.

The study findings will be used to develop understanding of the different influences and pressures that NHS clinicians experience.

The applicants will undertake review of video recordings of NHS staff meetings held in the South London and Maudsley NHS Foundation Trust. Confidential patient information is not required to meet the aims of the study, however the researchers may be exposed to confidential patient information when reviewing the recordings.

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

Confidential patient information requested

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

Cohort	Patients aged between 18 and 75 years whose care is discussed at Psychology & Psychotherapy Leads Meeting, Covid Meeting, Reflective Practice Meeting, Monthly Service User Involvement Group Meeting, Carers Group Meeting, Inpatient Managers Meeting, Performance and Quality Meeting, Referral Meeting. All meetings will take place within South London and Maudsley NHS Foundation Trust between 01/03/2022 – 01/04/2022. Up to 7 meetings would be recorded, but the applicants could not estimate how many patients may be discussed at these meetings.
Data sources	4. Recordings of NHS staff meetings held at South London and Maudsley NHS Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information will be used for linkage purposes.
Identifiers required for analysis purposes	No items of confidential patient information will be used for analysis purposes.

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

1. **Provide further details on how the results of the study will be used to improve or inform patient care, in order to justify the public interest and medical purpose.**

The aim of the study is to make mental health clinicians more aware of the external pressures affecting clinicians day to day negotiations regarding the care of service users and make clinicians more aware of external pressures governing their everyday service-level decisions.

The applicant explained that the study results will be fed back to selected meetings attended via the Research Team's presentation and will be more broadly available via a research repository and hopefully a published research article.

The CAG noted this information and raised no further queries.

2. **Provide further justification on why the meetings need to be recorded and transferred to the Kent and Medway Trust for transcription, rather than the researcher travelling to South London and Maudsley NHS Foundation Trust to transcribe the recordings, so that no recordings need to be transferred.**

South London and Maudsley NHS Foundation Trust (SLaM) was selected as the Project Supervisor is employed by SLaM. He will record selected meetings that he routinely attends for the purposes of this study via inbuilt computer software. The meetings will most likely be held virtually, with attendees/participants accessing the meetings remotely. The supervisor will share the link to meetings recordings with the student/lead researcher via the NHS email. The student/lead researcher who will be transcribing the meetings is not a SLaM employee and will be on placement with the Kent and Medway Trust at the time of data collection. Therefore, her NHS email account that she will receive the link via will be associated with the Kent and Medway Trust email account.

Her NHS encrypted laptop that will be used for the transcription will be provided by the Kent and Medway Trust. Technically speaking, this means that the data will be transferred to and transcribed in Kent and Medway Trust as the lead researcher will

be using email and equipment governed by the Kent and Medway Trust but there will be no physical transfer or travel involved to transcribe these meetings as they will be 'transferred' (i.e. email link sent to lead researcher) and transcribed remotely.

The CAG noted this information and raised no further queries.

3. **The poster needs to be revised as follows;**

    a. **An explanation of the SLAM acronym needs to be included.**

    b. **The opt-out process needs to be explained.**

    c. **A postal address needs to be provided for queries or requests to opt-out.**

    d. **The poster needs to explain that video recordings will be made of virtual meetings.**

A revised poster was provided, which addressed the above points. The CAG reviewed the poster and raised no further queries.

4. **Clarify if the dates that the recordings will take place have been revised, as the start date given in the application has now passed.**

The applicants advised that the data collection will take place between May and December 2022. The CAG noted this information and raised no further queries.

5. **Confirm that Surrey and Borders Partnership NHS Foundation Trust is the applying organisation.**

The applicant confirmed that Surrey and Borders Partnership NHS Foundation Trust is the applying organisation. 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 13 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 2020/21 DSPT review for South London and Maudsley NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 March 2022).

d. 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	
Dr Murat Soncul	CAG Alternate Vice Chair
Mrs Diana Robbins	CAG member
Dr Rachel Knowles	CAG member
Ms Sophie Brannan	CAG member

Context

Purpose of application

This application from the University of Manchester sets out the purpose of medical research that seeks to estimate the prevalence and incidence of musculoskeletal (MSK) conditions in Salford and the burden on medication and healthcare use, to identify the factors that predict patients with a secondary care diagnosis of axial spondyloarthritis (AxSpA) and to evaluate the comparative safety of hospital prescribed opioids.

The study will take place over 18 months. Primary and secondary care data will be collected for the patient population of Salford. Staff employed at NCA will extract, link and de-identify the data on behalf of the research team. Although the Business Intelligence Team at NCA access secondary care data routinely for planning and research, they do not usually access the Salford Integrated Record (SIR) primary care dataset. CAG support is requested to provide a legal basis for access to the SIR dataset.

Confidential patient information is extracted from the SIR and hospital data sources via an automated process. The Business Intelligence Team at NCA will link the data from the SIR and hospital data using NHS numbers and will hash the NHS number to create a de-identified dataset. Support is required for this as, while the Business Intelligence Team at NCA access secondary care data routinely for planning and research, they do not usually access the primary care (SIR) dataset. CAG support is requested to provide a legal basis for access to the SIR dataset and for the BI team to retain the hashed algorithm until the end of the study. The de-identified dataset which is then made available to UoM researchers in a project-specific space in NCA datalake.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over with a diagnosis of rheumatoid arthritis and ankylosing spondylitis are the subject of the research. Records for all patients registered with a GP in Salford between 2010 and 2020 will be screened and potentially included. The Salford Primary Care sample size is 250,000.
Data sources	1. Salford Integrated Record (SIR), primary care data 2. Secondary care data – outside the scope of support
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth
Identifiers required for analysis purposes	1. Postcode – district 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. **Provide confirmation that contact details for patients to register dissent would be included on all patient notification materials.**

The applicants confirm that contact details for patients to register dissent will be included in patient notifications. The CAG review the revised documents and noted that only an email address was provided for patients to register dissent. Members agreed that telephone, email and postal contacts also needed to be provided.

2. **The notification document needs to be reviewed for accuracy.**

The notification was reviewed for accuracy and revised accordingly. The PPIE group reviewed the notification at the workshop on 07 April 2022. The CAG reviewed the revised documents and was satisfied by the changes, provided that the contact details are revised as above.

3. **Feedback from patient and public involvement, including discussion of the use of confidential patient information as proposed in the application and involvement focused on people with directly relevant experience, needs to be provided.**

The applicants provided feedback from a patient and public involvement workshop run on 07 April 2022. The CAG reviewed this and was satisfied by the 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. The patient notification materials need to be revised to include telephone, email and postal contacts, should patients wish to dissent. Please provide the revised notification materials within 30 days of the issuing of this letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 10 February 2022.**

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

   The NHS Digital **2020/21** DSPT reviews for **the University of Manchester and the Northern Care Alliance** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 27 January 2022).

e. 21/CAG/0125 – ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections

Name	
Dr Tony Calland MBE	CAG Chair
Dr Sandra Duggan (written comments)	CAG member
Dr Liliane Field	CAG member
Mr. Myer Glickman OBE	CAG member
Mr Tony Kane	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Professor Sara Randall	CAG member
Mr Marc Taylor	CAG member

Context

Purpose of application

This application from the University of Liverpool (with the controller for the activity confirmed to be the University of Oxford) set out the purpose of medical research which aims to develop an understanding of disease processes in patients infected with severe emerging infections of public health concern.

Infectious disease is the single biggest cause of death worldwide. New infectious agents, such as the recent SARS coronavirus (SARS-CoV-2), continually emerge and require new investigations to understand how the disease works and how it interacts with the person infected. This study is designed to conduct rapid, pragmatic clinical investigation of patients with severe emerging infections of public health interest. It has been designed to collect and share as much data as possible, in a format that can be easily aggregated, tabulated and analysed across many different settings. The study is also designed to have flexibility to ensure that novel emerging pathogens can be accommodated.

The study has three tiers of activity, Tiers 0, 1 and 2. Tier 0, in which routine health care data will be collected and linked to other datasets, falls under the scope of this

application as consent will not be sought from patients. Tiers 1 and 2 will collect information with consent, and are outside the scope of this application.

Confidential patient information is required by people considered outside of the direct care team to input the study data into the REDCap database held by the University of Oxford.

Confidential patient information is required for linkage of CCP-UK research data to data held by NHS Digital and ICNARC via NHS number.

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	Individuals in the UK, male and female, and of all ages, who have confirmed infection with or high suspicion of infection with a pathogen or exposure to agents of public health interest.
Data sources	1. NHS Trusts 2. NHS Digital: a. Hospital Episode Statistics b. General Practice Extraction Service c. Record level 111 data d. Secondary Uses Service (SUS) e. mental health services data set f. emergency care data set (ECDS) g. improving access to psychological therapies data set h. National Diabetes Audit i. COVID-19 vaccination status and vaccination adverse reactions j. Civil Registration - deaths (cause of death lines) 3. Intensive Care National Audit and Research Centre (ICNARC)

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 – unit level 3. Gender 4. Occupation 5. Ethnicity
Additional information	The application is currently for COVID-19 investigations, however, the applicants may in future extend the support further via an amendment, to cover cases or outbreaks of any pathogen of public health interest.

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. To create a more comprehensive notification strategy, to be rolled out online. Please provide further details of the revised notification strategy in your reply.

A patient notification form has been drafted providing information on the following:

- What the study is

- What data is collected in the study

- Reason for the study being allowed to collect data without consent (please note this section advises the reader that the study has CAG s251 approval. This was done in order to have the document that will be facing patients after CAG s251 approval is received approved by REC/HRA. This document will not be circulated

until CAG s251 approval is received so this statement will be accurate if/when the document is made available to sites/participants)

- Outcomes the study has achieved

- How data collected is kept safe

- How to opt-out of data collection (local and National Data Opt-Out covered)

This document has been submitted to REC/HRA for approval as a substantial amendment. Once approval has been obtained, the document will be circulated to sites via the NIHR Clinical Research Network to make the document available on participating Trust websites.

2. To develop mechanisms to apply both the National Data Opt-Out and a local opt-out.

We confirm that the National Data Opt-Out will be applied using the Check for National Data Opt-Outs service for any participants recruited/data transferred after the transfer from COPI to CAG s251 takes place.

We have a local opt-out in place whereby individuals can email us at ccp@liverpool.ac.uk to request that their data be removed from the study.

3. To amend the current privacy notice to include reference to both the National Data Opt-Out and a local opt-out.

The privacy notice has been amended to confirm that a local opt-out and the National Data Opt-Out apply. The 'How to opt out' section of the privacy notice reads as follows:

"If after reading this you wish to opt out of this study by having your data removed please email ccp@liverpool.ac.uk including your name, date of birth, NHS number, and post code. We will look for your details in our data and if we find it we will delete it. In any case we will email back to you within 14 days to tell you if we found your data and if we did to confirm that your data has been removed. If you have signed up to the National Data Opt-Out and you are recruited after the expiry of the COPI notice on 30th June 2022, your data will be removed from the study."

This can be reviewed at our website https://isaric4c.net/privacy/

4. To confirm that the privacy notice will be displayed on the ISARIC website, participating Trust websites, and the data controller's (University of Oxford) website.

The amended privacy notice is displayed on the ISARIC website. When the patient notification form is approved by REC/HRA and ready to be circulated to sites requesting that it be made available on Trust websites, we will simultaneously request that the privacy notice be made available on Trust websites also. We believe requesting both of these at the same time will reduce potential confusion from sites and burden on the NIHR Clinical Research Network facilitating this. We are currently liaising with the University of Oxford to ensure the privacy notice is made available on their website also.

5. To conduct PPI within 2 months of the date of this letter, with the outputs from the PPI clearly described in response.

We drafted an online survey which was circulated by the NIHR's Research Champions network and a young person's working group (GenR YPAG). The survey received 40 responses.

The online version of the survey can be viewed at https://form.jotform.com/220522367740047

6. To accept that study data containing identifiers could be stored for 5 years from the date of support.

This is accepted.

7. To provide justification for any continued storage of identifiers after the 5 years have elapsed.

It is noted that we must provide justification for any continued storage of identifiers after the 5 years have elapsed.

8. That any patient facing documents referring to retention of 'minimal identifiers' should be amended to state what identifiers were being retained and the word 'minimal' should be removed.

We confirm that no patient facing documents contain the term ‘minimal identifiers’ and what identifiers are retained is stated on patient facing documents e.g. patient notification form.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Support is only given for research for Covid-19 purposes. In order to access confidential patient information outside of the COPI Notice, once it expires, and to study outbreaks of any pathogen of public health interest, then separate applications to the CAG would need to be made, unless a COPI Notice was issued for any of these pathogens.

2. Support under Regulation 5 Health Service (Control of Patient Information) Regulations 2002 will come into effect automatically following expiry of the COPI notice.

3. The National Data Opt Out will apply to processing of Confidential Patient Information under Regulation 5

4. Favourable opinion from REC **Confirmed 02 March 2013. Amendment submitted to REC in May 2020 to include the collection of identifiable data (incl. NHS numbers) without consent under COPI/CAG s251 support.**

5. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The applicant must ensure that NHS Digital confirmation of 'standards met' for organisations processing confidential patient information is in place once support under Regulation 5 is active.**

e. 22/CAG/0034 - Artificial Intelligence Stress Echo (FINESSE)

Name	
Dr Tony Calland MBE	CAG Chair
Dr Malcolm Booth	CAG member
Dr Patrick Coyle	CAG vice-chair
Dr Sandra Duggan	CAG member
Mr David Evans	CAG member
Professor Lorna Fraser	CAG member
Dr Katie Harron	CAG member
Dr Harvey Marcovitch	CAG member
Professor Sara Randall	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Context

Purpose of application

This application from the Milton Keynes University Hospital NHS Foundation Trust set out the purpose of creating a research database to be used to conduct a 15 year follow up of patients who underwent stress echocardiography using a pharmacological agent.

Stress echocardiography using a pharmacological agent, dobutamine, is a bedside test with good tolerability and accuracy, and which relies on the recognition of regional wall motion abnormalities at rest and during progressive stages of dobutamine administration. The FINESSE Stress Echocardiography (SE) database currently contains data from over 3000

patients who underwent SE for chest pain assessment at Milton Keynes University Hospital (MKUH) by a single Cardiologist over a 15-year period. The database was initially set up for audit purposes. In 2019, the applicants submitted a Research Ethics application to convert the database to a research database and to collect follow-up data for patients. The applicants are now applying for support under s251 in order to undertake linkages to NHS Digital in order to follow-up patients.

The applicants seek support for the disclosure of confidential patient information from the FINESSE Audit Database at Milton Keynes University Hospital NHS Foundation Trust to NHS Digital for linkages to NHS Digital held datasets. NHS Digital will apply a Unique Research ID to patient records before returning the now pseudonymised, linked dataset to Milton Keynes University Hospital NHS Foundation Trust. The dataset will then be anonymised prior to use in analysis.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over who underwent SE for chest pain assessment at Milton Keynes University Hospital between 01/10/2002 - 01/12/2017.
Data sources	5. The FINESSE Audit Database, held by Milton Keynes University Hospital NHS Foundation Trust 6. NHS Digital held datasets: a. Hospital Episode Statistics (HES) database b. Office for National Statistics (ONS) database c. Hospital Admitted Patient Care (APC) database d. A&E Attendances and Emergency Admissions (AE) database
Identifiers required for linkage purposes	3. Name 4. NHS number 5. Hospital ID number 6. Date of birth 7. Year of birth 8. Date of death 9. Gender

Identifiers required for analysis purposes	2. Full Name 3. NHS Number 4. Hospital ID number 5. Date of birth 6. Year of birth 7. Date of death 8. Gender

Confidentiality Advisory Group advice

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

1. **An updated and clear data flow diagram needs to be provided. This needs to explain the specific data items needed for linkage and the information returned.**

The applicant provided an updated data flow diagram. This noted the specific data items needed for linkage (NHS number, unique research ID) and the data to be retrieved (cause of death, non-fatal MI, Stroke, unplanned revascularisation). The CAG were content with this response.

2. **Clarify whether the Natural Language Programming will be undertaken internally at Milton Keynes University Hospital NHS Foundation Trust, or if a third-party would be involved.**

The applicant confirmed that Natural language programming is no longer required for the research project, and the CAG were content with this response.

3. **Clarify whether dates of death needed to be retained, or if this could be converted to be less identifiable, such as age at death, or survival rate used instead.**

On reading the applicants response, the CAG were unclear at what point the date of death is converted to age at death. This was further discussed with the applicant who confirmed that although date of death would not be converted to age at death, as this was not useful for his analysis, this would be converted into month and year of death, as soon as possible after linkage with NHS Digital had been undertaken. The applicant hoped this would be September 2022, but it is not possible to confirm dates. The CAG were content with this response.

4. **Patient notification needed to be undertaken prior to the data linkage taking place, so that patients could dissent to use of their data in the study. Details of the opt-**

out mechanism, including postal, email and telephone contacts, need to be included in the patient notification documents.

The applicant provided patient notification documents including a poster, website notification on the Milton Keynes University Hospital Website, and via social media through the Milton Keynes University Hospital Twitter page. The CAG were content with this response.

5. **Further patient and public involvement needs to be undertaken around the change from a database for internal use only to a research database. Discussion of the proposed data linkages also needs to be included.**

The applicant confirmed that a discussion took place on 7 April 2022 via Zoom with the Trust's Patient representatives, and has provided the minutes. It appears that 2 patient representatives were present. The Patient representatives were supportive of the uses of confidential patient information without consent. The CAG commented that although patient and public involvement had been undertaken, and this was now sufficient to begin the activity, the Members commented that the patient and public involvement activity was limited. A condition of support has been applied to extend this engagement, given the subject matter is AI. The applicant is requested to report on the further patient and public involvement undertaken, at annual review.

6. **The process to be followed for applications to use the database needed to be provided. This needs to include details on who would review applications to ensure that the request was justified.**

A process for applications to use the database is now in place. A flow chart has been provided, and has been reviewed and approved by the Milton Keynes University Hospital Information Governance department and was discussed and approved by the Patients representatives. 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. Please undertake further patient and public involvement, and report on the further patient and public involvement undertaken at annual review.

2. Favourable opinion from a Research Ethics Committee. **Confirmed: 08 February 2022**

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

   The NHS Digital **2020/21** DSPT reviews for Milton Keynes University Hospital NHS Foundation Trust and NHS Digital were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 March 2022).

1. New Amendments

19/CAG/0161 - CRYOSTAT-2: A multi-centre, randomised, controlled trial evaluating the effects of early high-dose cryoprecipitate in adult patients with major trauma haemorrhage requiring major haemorrhage protocol (MHP) activation

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating trusts to the NHS Blood and Transplant Clinical Trials Unit and then the onward disclosure to NHS Digital and the Trauma and Audit Research Network (TARN) to facilitate linkage and follow-up. This support extended only to the sub-cohort of patients who had not previously been approached to provide consent for their ongoing inclusion in the trial and those who had

subsequently died, and to all patients who are enrolled but from whom informed consent is not obtained for their ongoing inclusion in the trial.

In this amendment, the applicants are seeking to make four changes. The first and second changes are to include additional data from TARN; quality of life data for the patients in-hospital stay, where it has not been possible for the hospital research team to collect this data, and the collection of injury severity data. This additional data will be retrospectively collected for all patients except those who have withdrawn and have requested that their data not be included or requested that that their data be deleted.

The applicants also seek to increase the number of patients from 1142 patients to 1556. The applicants explained, due to the impact of the Covid-19 pandemic on recruitment in the USA, fewer patients had been recruited in the USA and a greater number in the UK were recruited to make up for this shortfall. The letter confirming support under s251 did not state a specific number, as it had not been possible to predict how many patients would be included, however the applicants wanted to update the CAG on how many patients were included under support.

The applicants also seek to extend the duration of the study to 31 August 2022.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that the duration extension 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:

- **Trauma and Audit Research Network has a confirmed 'Standards Met' grade on DSPT 2020/21 (Checked via tracker on 19 April 2022),**
- **NHS Digital has a confirmed 'Standards Met' grade on DSPT 2020/21 (Checked via tracker on 19 April 2022),**
- **NHS Blood and Transplant Service a confirmed 'Standards Met' grade on DSPT 2020/21 (Checked via tracker on 19 April 2022).**

2. Confirmation of a favourable opinion from a Research Ethics Committee.
Confirmed: 17 March 2022.

19/CAG/0047– Development and validation of a risk assessment tool for self-harm in prisoners.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study has support to allow access to prisoner health records by a research assistant to extract wider clinical information necessary for analysis. 'S251' support is in place for this access in a variety of ways, including in person, accessing ACCT records via a link person, extracting data from electronic prison healthcare notes (SystmOne), and accessing Prison National Offender Management Information System (NOMIS) data.

The amendment sought support to extract one further data item from SystmOne records; '*Are details of the ACCT recorded in SystmOne'* (there will only be a 'yes' or 'no' response). The applicant has confirmed that by collecting this one additional data item, applicants will be able to see if self-harm and suicide risk information is routinely communicated between residential and healthcare departments. The applicants reason that this is essential to enable better management of suicide and self-harm risk within the prison, as information sharing is key to risk identification and management.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT). The purposes of this amendment do not deviate from the original support provided, and appear to

be within the remit of the original ‘s251’ support, as the addition of this data item is not any more disclosive.

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 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 **20/21** DSPT reviews for **Greater Manchester West Mental Health NHS Foundation Trust, Mersey Care NHS Foundation Trust, Tees, Esk and Wear Valleys NHS Foundation Trust, Spectrum Community Health CIC, and The Phoenix Partnership (Leeds) Ltd** were confirmed as ‘**Standards Met’** on the NHS Digital DSPT Tracker (checked 12 April 2022

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 14 April 2022

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 Kathleen Cassidy	HRA Confidentiality Advisor

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.

In the original application to CAG, the applicants had listed Queen Elizabeth Hospital King's Lynn NHS Foundation Trust in error. The applicants sought to remove this site and include Lewisham and Greenwich NHS Trust as a data processor.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT agreed that the amendment did not affect the scope of the support in place and that the change 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. 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 **2020/21** DSPT review for **the below organisations** were **confirmed** as 'Standards Met' on the NHS Digital DSPT Tracker (06 May 2022):

   - London Ambulance Service NHS Trust
   - King's College Hospital NHS Foundation Trust
   - Barts Health NHS Trust
   - Guy's and St Thomas' NHS Foundation Trust (includes Royal Brompton and Harefield NHS Foundation Trust)
   - St George's University Hospital NHS Foundation Trust
   - Royal Free London NHS Foundation Trust

- Homerton University Hospital NHS Foundation Trust
- Chelsea and Westminster Hospital NHS Foundation Trust
- Dartford and Gravesham NHS Trust
- Imperial College Healthcare NHS Trust
- Kingston Hospital NHS Foundation Trust
- Croydon Health Services NHS Trust
- Epsom and St Helier University Hospitals NHS Foundation Trust
- Central and Northwest London NHS Foundation Trust
- Lewisham and Greenwich NHS Trust

20/CAG/0073 – Assessing the cancer risks due to occupational exposure to styrene

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Dr Tony Calland, MBE	CAG Chair

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from the Health and Safety Executive (HSE) to Institute of Occupational Medicine (IOM), for IOM to provide confidential information to NHS Digital in order for NHS Digital to provide cancer and mortality data back to IOM.

In the initial application, the applicants sought support for the HSE to disclose confidential patient information, including full date of birth, to the IOM who would then further disclose this information to NHS Digital. The return of the linked dataset from NHS Digital to IOM contained patients month and year of birth, instead of the full date of birth.

The applicants now seek to include patients full date of birth in the disclosure from NHS Digital to IOM. This has been requested by NHS Digital, so that the applicants can check the accuracy of the matching, based on NHS Digital's experience from previous study, where errors have occurred.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that the amendment was in the public interest, as it would enable the accuracy of the linked dataset to be more thoroughly checked.

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. Favourable opinion from REC. **Confirmed non substantial 10 May 2022**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **Institute of Occupational Medicine and NHS Digital (checked on DSPT tracker 09 February 2022) have been confirmed as 'Standards Met' by NHS Digital.**

14/CAG/1012 – Critical Care Health Informatics Collaborative

Name	Capacity
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study is a research database including clinical, laboratory and demographic data in relation to all patients admitted to Adult Critical Care Units across multiple NHS Trusts. Support is currently in place to allow access to data from hospital systems and for linkage with Hospital Episode Statistics (HES) data held by NHS Digital.

This amendment sought support to restructure to the database from an XML to an OMOP common data standard, which will bring it into line with other similar databases. The requested change is no more disclosive, and there appear to be no changes to data flows/processors/items/purposes.

Confidentiality Advisory Group advice

The amendment requested was considered by the Vice-Chair, who was content to recommend support for this amendment. The Vice-Chair was reassured by the amendment application that this is a restructuring of the database within the UCL safe-haven; that the bronze level containing identifiers will never be accessible to researchers, that the silver level will only be accessible to employees of NHS organisations whose patients' that particular data refers to, and gold level, which is pseudonymised, will only normally be accessible through a thin client. Any other release, still pseudonymised, will be under strictly controlled circumstances.

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: University College London – School of Life and Medical Sciences has confirmed 'Standards Met' assurance on DSPT 2020/21 (by check of NHS Digital DSPT Tracker on 11 May 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 25 April 2022

21/CAG/0008 – Clinical Practice Research Datalink (CPRD)

Name	Capacity

Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from data processors (listed below) to NHS Digital as a trusted third party in order to link datasets and provide CPRD (MHRA) with effectively anonymised data.

In this amendment, the applicants seek to remove Dr Janet Valentine as Director of CPRD, as she left the organisation in October 2021. Drs Puja Myles and Tim Williams will take on the role of Joint Directors of CPRD on a temporary basis. A further amendment will be made once the post has been substantively filled.

The applicants also sought to revise the wording on the posters to be displayed in GP practices. The REC had asked that the wording of the poster was revised when the applicants submitted an updated application in 2021. The draft text of the revised poster was provided.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group, who were content to provide support for these changes.

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 2020/21 DSPT review for NHS Digital was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 19 April 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 11 May 2022

16/CAG/0053 – Prolonged Effects of ART: A Record Linkage study (PEARL)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from University of Oxford aims to create a linked dataset combining data on fertility treatment from the Human Fertilisation and Embryology Authority (HFEA) and primary care and hospitalisation data from the Clinical Practice Research Datalink (CPRD), and to use the linked dataset to assess the effect of Assisted reproductive technologies (ART) on the health of women and their children after successful fertility treatment.

This amendment sought to extend the duration of support to 31st December 2023. Without a duration amendment the applicants would be unable to complete the analysis and address the original research questions.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team consider the justification for the amendment to be reasonable.

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 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 – 2020/21 DSPT for University of Oxford – Medical Science Division – Nuffield Department of Population Health was confirmed as 'Standards Met' by NHS Digital (by check of DSPT tracker 12 May 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 25 April 2022

22/CAG/0009 – Early detection of bladder cancer in Yorkshire: Feasibility assessments for implementing a targeted study in populations with high disease specific mortality risk

Name	Capacity
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating GP practices to iPlato Healthcare, for Cohort 2, and to the Participating NHS Trust Research Team, for Cohort 3, and to King's College London for both Cohorts, and then to Testcard Ltd, who will undertake the mailout to selected participants, and support to

disclose confidential patient information to NHS Digital for linkage to NCRAS for follow-up data.

In their initial application the applicants had stated that confidential patient information collected for patients who do not respond to the invitation would be deleted after 8 weeks. The applicants now seek to retain this information until the end of active recruitment, which is estimated to be 14 months after the sending of initial invitations.

The applicants explained that deleting confidential patient information after 8 weeks was not practicable, as the invitations for patients in Cohort 3 would be sent ad-hoc, whenever an eligible patient was identified. This would make tracking and management of the deletion of data difficult and presented a risk that data may be retained for longer than 8 weeks. The applicants therefore argued that retaining this data for a longer period and applying the apply the same approach to the retention and deletion of personal data for all three cohorts would be less risky from a data management perspective.

The applicants noted that they would like to apply the same approach to the retention and deletion of personal data for all three cohorts, as they believe retention for 14 months is less risky from a data management perspective and to ensure consistency across the three cohorts.

The applicants also noted that, while participants will be asked to return their self-test kits as soon as possible, there was the potential for a patient to return the test several months after receiving the testing kit. Alternatives, such as advising those approached to send within a set timeframe or asking patients to provide contact details when returning the kit were not feasible as, whilst the study App could be designed to collect contact details, this would not be possible with the freephone system and would require a third party collecting personal data (app and freephone data collection is currently pseudonymised).

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Vice-Chair was content to recommend support for this amendment, noting that the applicants have made a good case for retaining the details of non-responders and deleting them all together at 14 months.

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

   The NHS Digital **2020/21** DSPT reviews for Testcard Ltd, King's College London and NCRAS (held by NHS Digital) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 19 April 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 21 April 2022

20/CAG/0009 – The Cambridge Cohort

Name	Capacity
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow research staff to undertake the processing of confidential patient information from patient records at Cambridge University Hospitals NHS Foundation Trust, in order to provide the applicants at the University of Cambridge with an anonymised dataset.

In this amendment, the applicants sought to increase the size of the cohort from 150,000 to over 250,000. This increase is required due to the increased numbers of women screened over the study time period as a result extending the age eligibility criterion as well as variation in size of the number of women screened between the two sites involved. An amended lay summary and protocol were provided.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Vice Chair was content to recommend support for this amendment, noting that the applicants have more mammograms available because they have extended the age range of eligibility, so they would like to include the additional mammograms – up from 150,000 to 250,000 which the Vice-Chair is sure will improve accuracy of the analysis.

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 2020/21 DSPT review for Cambridge University Hospitals NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 06 May 2022).

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed REC do not need to review 06/05/2022

21/CAG/0097 – PARADISE: Predicting AF after Cardiac Surgery - A Clinical Prediction Rule for Post-operative Atrial Fibrillation in Patients Undergoing Cardiac Surgery

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application seeks to develop and validate two prognostic models to predict post-operative atrial fibrillation after cardiac surgery. ‘s251’ support is currently in place to allow staff outside the direct care teams at Liverpool Heart and Chest Hospital and Barts Health NHS Trust to process confidential patient information in order to identify suitable patients and collate a dataset from multiple data sources, and the disclosure of confidential patient information from the Liverpool Heart and Chest NHS Foundation Trust and Barts Health NHS Trust to NHS Digital, for NHS Digital to apply the National Data Opt-Out.

This amendment sought support for the addition of Oxford University Hospitals NHS Trust as an additional site, as an additional data processor for this application, and therefore an additional data source. Commencing data extraction from the originally planned sites has been delayed. To mitigate the risk to the PARADISE project applicants want to add Oxford University Hospitals NHS Trust as a third site, in order to meet recruitment targets.

Applicants have updated the patient notification document and patient poster to reflect the addition of Oxford University Hospitals as an additional site. The patient notification has additional minor corrections and updates.

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 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 20/21 NHS Digital DSPT reviews for Nuffield Department of Clinical Neurosciences, University of Oxford, Barts NHS Trust, Liverpool Heart and Chest NHS Foundation Trust, Oxford University Hospitals NHS Foundation Trust, and NHS Digital were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 12 May 2022)**

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

17/CAG/0058– National Chronic Kidney Disease Audit

Name	Capacity
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The National Chronic Kidney Disease Audit (NCKDA) collected data between 2014-2016 from 1057 general practices in England and Wales on testing of patients at risk of chronic kidney disease, as well as the identification and management of patients with chronic kidney disease. This application has support to allow the data to be used in future research of long term outcomes of audit participants.

This amendment sought support to extend the duration of 's251' support for the NCKDA research database for 5 years until 2027, to allow further research to take place and address delays encountered due to the pandemic. The amendment also sought support to send confidential patient information from the University College London (UCL) Safe Haven to the

UK Renal Registry (UKRR) for linkage with UKRR data. The linkage will enable applicants to study clinically-important long term outcomes such as end-stage renal disease (ESRD), dialysis, death, and kidney transplantation.

The applicant has also provided updated REC and IRAS references due to the five year support period provided to research databases.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair was content to recommend support for this amendment. The Vice-Chair noted that the duration request is justified because this kind of longitudinal study needs a long time to fulfil its full potential. The link to UKRR is one that CAG would have expected the application to already have, noting that it seems they have been receiving this data via NCOR, via another route, and there is now an administrative problem with that methodology. In the original recommendation it was anticipated that further linkages might be needed, and the Vice-Chair stated that this new more direct linkage with UKRR seems fully justified.

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 **20/21** DSPT review for **UCL School of Life and Medical Sciences Data Safe Haven** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 16 May 2022)

   The NHS Digital **21/22** DSPT review for **The Renal Association** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 16 May 2022)

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

ECC 2-03(c)/2012 – National Paediatric Diabetes Audit (NPDA)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants are seeking to extend the duration of 's251' support to 01 May 2025, to align with the new contract with HQIP. There is a possibility of extension for a further 2 years post May 2025.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT 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 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 – Royal College of Paediatrics & Child Health, Net Solving Limited, Rackspace Ltd, and SysGroup PLC have confirmed 'Standards Met' grade on DSPT submission 2020/21 by check of the NHS Digital DSPT tracker on 12 May 2022**

18/CAG/0119 – Comprehensive Patient Records (CPR) for Cancer Outcomes: A feasibility study Workstream 5: Patient Reported Outcome Measures (PROMs)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Leeds aims to investigate the long-term effects of cancer and cancer treatment. The specific work stream which is presented in this application (Work Stream 5) relates to the collection of PROMs (Patient Reported Outcome Measures) data from patients around their opinions on their health, treatment, quality of life and other issues. This information is linked with the wider clinical information collected throughout the study to create a comprehensive patient record, showing the long-term effects of cancer of quality of life, health and wellbeing.

This amendment sought support to extend the duration of 's251' support until November 2022, to allow the full linkage required to be undertaken, and analysis completed.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. No queries were raised regarding this amendment 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 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 20/21 DSPT review for **Leeds Teaching Hospitals NHS Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 May 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non-substantial 27 April 2022**

21/CAG/0070 – The DAMPen-D study: Improving the Detection, Assessment, Management, and Prevention of Delirium in Hospices - Co-design and feasibility study of a flexible and scalable implementation strategy to deliver guideline-adherent delirium care

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to establish whether it is feasible to collect sufficient outcome data, explanatory process data, and cost data, in a future effectiveness evaluative study in palliative care settings. Support is in place to allow members of the research team from the University of Hull, who are not members of the direct care team, to access confidential patient information, held in paper or electronic records, for the three participating hospice sites in order to extract an anonymised dataset.

This amendment sought support to extend the duration of 's251' support until 15 February 2023, in order to complete the study.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the 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: Security assurances are required for the sites 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 the applicant to ensure that appropriate security assurances are in place.**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 13 May 2022**

18/CAG/0102 – HES and NICOR data linkage for cardiac failure population analysis

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants sought support to extend the duration of 's251' support until 10 May 2023, due to delays to the project caused by the Covid-19 pandemic.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory 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 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 **King's Technology Evaluation Centre** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (Confirmed via email to CAG inbox 19 May 2022)

   & The NHS Digital **20/21** DSPT review for **NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (Checked 16 May 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee – **Confirmation non substantial 10 May 2022**

18/CAG/0100 – HPS-4/TIMI 65/ORION-4: A double-blind randomized placebo-controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to process confidential patient information supplied by acute hospitals trusts and NHS Digital to the Clinical Trial Service Unit at the University of Oxford in order to contact patients to seek consent to include their data on a pre-screening database.

Previous amendments, seeking support for the addition of Paragon Customer Communications Ltd as a data processor, to facilitate the sending of a second invitation letter to patients who did not respond to the first contact attempt and to amend the wording of patient notification materials to make patients aware they may be contacted twice, have been supported.

In this amendment, the applicants are seeking to make changes to the protocol, to reflect changes in the eligibility criteria. The age-based eligibility criterion for men will be lowered to include those aged 40 years or over. The age-based criterion for women will remain those aged 55 years and over. The point-of-care total cholesterol threshold required at screening to enter the run-in has also been reduced from ≥ 3.5mmol/L (135mg/dL) to ≥3.0mmol/L (116mg/dL).

The protocol, participant invitation letter, participant re-invitation letter and GP Run-in letter have been revised to reflect these changes. An updated video will also be made available on the ORION-4 website and the proposed script was included in the amendment.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT agreed that the changes made were minimal and did not impact on the scope of support.

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 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 2020/21 DSPT reviews for University of Oxford - Medical Sciences Division - Nuffield Department of Population Health and Paragon Group UK Limited were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 26 April 2022).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 22 April 2022.**

2. Annual Review Approvals

18/CAG/0131	Inflammatory Bowel Disease Registry
16/CAG/0134	Follow-up of the Hertfordshire Cohort Study through Hospital Episode Statistics
ECC 1-06 (c) /2011	National Gastrointestinal Cancer Audit Programme (Oesophago-Gastric Cancer)
ECC 1-04(b)/2010	Evaluating the age extension of the NHS Breast Screening Programme (AgeX Trial)
21/CAG/0042	The Wynn Database - Metabolic Risk Factors and Mortality
ECC 3-04(a)/2012	National Audit of Cardiac Rehabilitation (NACR)
18/CAG/0041	Liverpool Lung Project
21/CAG/0047	Neonatal Intensive Care Data to be provided to the National Pregnancy in Diabetes Audit (part of the National Diabetes Audit NDA)
16/CAG/0118	A Study of the Natural History of Renal Disease in TSC2/PKD1 Contiguous Gene Deletion Syndrome
18/CAG/0056	Retinoblastoma gene mutations and risk of second primary tumours
21/CAG/0084	National Cancer Patient experience survey 2021 (NCPES)
21/CAG/0070	The DAMPen-D study: Improving the Detection, Assessment, Management, and Prevention of Delirium in Hospices - Co-design and feasibility study of a flexible and scalable implementation strategy to deliver guideline-adherent delirium care
20/CAG/0009	The Cambridge Cohort – mammography East Anglia Digital Imaging Archive (CC-MEDIA)
18/CAG/0013	Evaluating the real-world implementation of the Family Nurse Partnership in England: a data linkage study
CAG 7-04(a)/2013	Use of GP data with commissioning data sets to support Risk Stratification
17/CAG/0082	Do specialist cancer services for teenagers and young adults (TYA) add value?
19/CAG/0223	TwinsUK: Phenotypic enrichment of the TwinsUK cohort through linkage to electronic health records and other databases

PIAG 1-05(e)/2006	Frequency of follow-up for patients with low-, intermediate- and high-risk colorectal adenomas
ECC 5-04(e)/2011	SIGGAR1 (Special Interest Group in Gastrointestinal and Abdominal Radiology): CT colonography, colonoscopy or barium enema for the diagnosis of colorectal cancer in older symptomatic patients
18/CAG/0102	HES and NICOR data linkage for cardiac failure population analysis
21/CAG/0061	British Paediatric Surveillance Study of Neonatal Stroke in the United Kingdom and the Republic of Ireland presenting/diagnosed in babies in the first 90 days of life
19/CAG/0162	Accuracy, impact and cost-effectiveness of prehospital clinical early warning scores for adults with suspected sepsis
ECC HFEA 5-04(b)/2010	Do hormonal treatments for assisted reproduction increase risks of cancer or mortality in women? A national cohort study
ECC 5-05(j)/2012	Long term risk of cervical cancer following a HPV infection
21/CAG/0050	Suicide in former service personnel: rates, antecedents, and prevention

Signed – Chair		Date
Minutes signed off as accurate by CAG Chair Dr Tony Calland MBE, Vice Chair Dr Patrick Coyle, and Alternate Vice Chairs Ms Clare Sanderson and Dr Murat Soncul		*11 July 2022*
Signed – Confidentiality Advice Team		Date
Ms Caroline Watchurst, HRA Confidentiality Advisor		*05 July 2022*