Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

02 December 2021

Held via Zoom

Present:

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

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Michael Pate	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **04 November 2021** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **04 November 2021** meeting applications.

3. COPI Notice Transition Application - research

a. 21/CAG/0180 - The National COVID-19 Chest Imaging Database (NCCID)

Context

Purpose of application

This application from NHS England (with the joint controllers for the activity confirmed to be NHS England and the Department of Health and Social Care) set out the purpose of medical research which aims to create a research database to be used to improve the identification and triage of Covid-19 patients.

The applicants have created the National COVID-19 Chest Imaging Database (NCCID) in response to the Covid-19 crisis. The database will be used to enable the validation and development of automated analysis technologies and to promote research projects in response to the Covid-19 pandemic. Data collection is happening across the country and the applicants are seeking to consolidate these individual data collection activities into a single national database, in order to avoid duplication of effort.

The main data collection involved is the collection of chest x-rays and CT scans and a small amount of relevant clinical information from NHS trusts throughout the UK which is transferred centrally to Royal Surrey County Hospital NHS Foundation Trust. Data is then linked with other datasets and transferred to the NCCID cloud storage for subsequent access by researchers.

Support is requested to allow staff at participating NHS trusts, who are not members of the direct care team, to access confidential patient information in order to identify participants and carry out the pseudonymisation process, before the pseudonymised data is transferred to the Royal Surrey NHS Foundation Trust for inclusion in the NCCID.

Support is required for participating NHS Trusts to transfer the encrypted NHS number with clinical data and images to the Royal Surrey Hospital. The image data and clinical data flow separately. The image data will contain the encrypted NHS number that the Royal Surrey Hospital has the ability to reidentify to apply the national data opt out and for linking with the NHS England Segmentation Database.

Support is required for NHS number to flow from the Royal Surrey Hospital to the NHS England Segmentation Database, in order to gain ethnicity data (for those where this is not recorded in data from Trusts). NHSE have to reidentify the NHS number in order to gain the ethnicity data to return back.

When setting up Trusts with the software to conduct the pseudonymisation process, Surrey have to test to make sure it is working. For many Trusts, this involves the Trust providing phantom data (i.e. no real data) to Surrey to test. However, some Trusts do not have this so, in this case, Trusts provide Surrey with hospital number of a sample

of patients in order to test the system. This is expected to continue past the expiry of the COPI Notice, so support for this is required, where necessary.

The Royal Surrey will send ISARIC and PHOSP-COVID hashed NHS numbers which those study teams will match with their own hashed NHS numbers. Support will not be needed for this, as the NHS numbers are not identifiable.

Although mentioned in the protocol, Faculty are no longer involved in the study and are thus not a data processor.

There is data processing in Scotland which falls outside of scope, with PBPP approval already in place.

A recommendation for class 1, 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	All patients aged between 12 and 109 years of age who present with suspected Covid-19 and who have had an RT-PCR swab.
Data sources	1. NHS Trusts 2. Royal Surrey Hospital SMART portal
Identifiers required for linkage purposes	<u>NHS trusts</u> 1. NHS number 2. Hospital number <u>SMART Portal</u> 1. NHS number <u>Royal Surrey Hospital</u> 1. NHS number

Identifiers required for analysis purposes	1. Date of death
Additional information	N/A

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Scope

The CAG noted that the application is currently relying on an alternative legal basis to process confidential patient information without consent, under the 'COPI notice' and that this will continue for its duration. The group therefore considered the elements of the project that are expected to be continuing following expiry of the 'COPI notice', and which require support under regulation 5.

The CAG was clear on the scope of support required.

The CAG decided that support was only provided for the setting up of the database, and that any separate research conducted using the data from the database should be a new application.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicants explained that consent was not feasible due to the potential size of the dataset, which they expect will contain data for 25,000 to 100,000 individuals. As well, many of these patients are likely to have died.

The CAG was content with this explanation.

Members understood that support was requested to use identifiable patient information to test the software, where no phantom data is available. Members were unclear on the number of identifiable patient records that would be needed to test the software and the practical alternatives that could be used instead of support. As such, clarity was requested on the number of patient records to be used for this aspect, as well as justification on why either phantom records could be created by the site, or consent could be given by the individuals.

- Use of anonymised/pseudonymised data

Although data is pseudonymised at the point of transfer from sites, the Royal Surrey Hospital will be able to reidentify through the encrypted NHS number.

NHS number needs to flow from the Royal Surrey to NHS England to obtain missing ethnicity data.

The CAG accepted this methodology.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The National Data Opt-Out is currently invoked by the Royal Surrey Hospital. Whilst this is following the breach of confidentiality the applicants have stated their reasons for this by the fact that the National Data Opt-Out is not fully operational and many Trusts have not set this up yet. It should be noted that under the COPI notice there is no requirement to apply the National Data Opt-out at all.

There is currently no local opt out but the applicants state that there are plans to implement this in the future. The CAG noted this and agreed a local opt-out mechanism should be in place by the time the COPI Notice expires.

The CAG noted that any opt-out was only applied after a breach of confidentiality at the Royal Surrey Hospital. The CAG was content with this, as it reduced the burden on the Trusts taking part.

The CAG reviewed the privacy notice and felt that it was too technical for the cohort of participants to understand. It was also not clear on the exact flow of identifiable data, so that participants were fully informed. The CAG agreed that the privacy notice be rewritten to describe the data flows more clearly, and to allow people to opt-out more easily. This should also include the option of opting out locally. The CAG agreed that Patient and Public Involvement should be used to redesign the privacy notice, which should involve a wider range of people than had been consulted thus far.

The CAG felt that steps should be taken to inform patients when seen at Trusts e.g. a poster displayed in imaging departments. As such, the applicants were requested to provide an example poster within Trusts which should include opt-out information.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants have undertaken 3 explanatory workshops with patients and members of the public. They had representation from useMYdata, Oxford Biomedical Research Centre, and Cambridge University Hospital NHSFT - Addenbrooke's Hospital. Following the workshops and recommendations from participants, the applicants have recently published further information for patients and the public - https://www.nhsx.nhs.uk/ai-lab/ai-lab-programmes/ai-in-imaging/how-patient-data-is-used-in-the-nccid/

The applicants also state in the response that “The Long Term Plan for PPI for NCCID - The NHS AI Lab - plans to run future workshops (based on uptake) in the next 10 months that will target the hospital trusts that have donated data but didn't participate in these patient and public engagement workshops. The invitation to these workshops will also extend to any additional trusts that have been onboarded to submitting data to the NCCID in the future.”

The CAG commented that the workshops seemed to be more about informing the public, rather than seeking their views on the acceptability of using identifiable data without consent.

The CAG would like further details about any PPI which has been conducted where the acceptability of using identifiable data without consent has been tested. This should detail how many people were involved, the questions they were asked, and what their views were. If none has been conducted, this should be conducted prior to expiry of the COPI Notice, with details provided to the CAG in response.

Exit strategy

Research database support is expected to be required for the next 3-4 years, potentially longer. Whilst there is no specific overarching exit strategy there are a number of controls in place to limit access.

The CAG understand that decrypted NHS numbers will be deleted once the data is linked, and that this likely to be an ongoing process. The CAG is content with this.

The CAG decided that support was only provided for the setting up of the database, and that any separate research conducted using the data from the database should be a new application. The CAG would like a justification for the continued collection of data once the database is established i.e. the collection that would occur outside of the COPI Notice.

Retention of Date of Death

The applicants have justified retention of the participant's date of death by saying - "We feel that due to the volume of data collected, the large number of collection sites and the limited number of additional clinical data points that DOD does not constitute an identifiable property. In addition, due to the unfortunate nature of the database's subject matter, there are a large number of deaths recorded, which, in combination with the volume of cases and sites, reduces the risk of DOD being identifiable. We acknowledge that if the research database was much smaller or had a more limited number of collection sites, this viewpoint might need to be re-assessed."

The CAG noted the reasons given by applicants but requested further detail about why the full date of death was required, including why it cannot be converted to a length of time since admission, or another variable which would not be identifiable.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. To confirm the number of patient records to be used to test the software, where no phantom data is available, as well as justification on why neither phantom records could be created by the site, or consent could be given by the individuals.
2. To provide a revised privacy notice which
    a) clearly describes the flows of identifiable data.
    b) allows people the opportunity to opt out, both nationally and locally.
    c) uses Patient and Public Involvement to aid in its revision.
3. To create a poster to include the options for opting out of the study, including a local option, and details of where they would be placed
4. To ensure that participating Trusts have a local opt-out mechanism in place at the time of COPI Notice expiry, which should include a record of those who have expressed a wish to have their data opted-out.
5. To provide details of any PPI which has been conducted which specifically addresses the use of identifiable data without consent.
6. To provide justification for the continued collection of data, once the database is established and the COPI Notice has expired.
7. To provide justification as to why the full date of death is required and why it cannot be converted into an unidentifiable format, such as ‘number of days since admission’.

Specific conditions of support

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Support was only provided for the setting up of the database, and that any separate research conducted using the data from the database should be a new application.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 17 April 2020.**

3. 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 (NHS Trusts and the Royal Surrey Hospital) is in place once support under Regulation 5 is active.** See below for further details.

b. 21/CAG/0125 - ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections

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

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Scope

The CAG noted that the application is currently relying on an alternative legal basis to process confidential patient information without consent, under the 'COPI notice' and that this will continue for its duration. The group therefore considered the elements of the project that are expected to be continuing following expiry of the 'COPI notice', and which require support under regulation 5.

Support is requested to allow the disclosure of confidential patient information from medical records, to those considered to be outside of the direct care team in participating NHS Trusts in England and Wales, for the purpose of patient identification and data input into the REDCap database, held by the University of Oxford.

Support is requested for CCP-UK data held in the University of Oxford REDCap database to be linked with NHS Digital data. This will be by NHS number. Once linked, the data will be pseudonymised by removing the NHS number and linking the data via ISARIC ID to the ISARIC4C data.

The applicants advised that data collected for the study will be retained, as it will be of potential value in the future should similar outbreaks of infectious disease occur. The applicants therefore seek support to retain the data indefinitely in the Edinburgh Data Safe Haven. This data will contain minimal patient identifiers, such as date of birth, ethnicity, NHS/CHI number and postcode.

Patients in Tiers 1 and 2 will be consented and are outside the scope of the support sought and support will not be required for staff who are part of the direct care team at NHS Trusts to enter data into the REDCap database.

Following linkage of CCP-UK clinical data with NHS Digital clinical data, the data is pseudonymised by removing NHS number and using the ISARIC study ID. The transfer of the linked data will be to the Scottish National Data Safe Haven or to the Integrated Analysis Platform, but no identifiers will flow.

Linkage of ISARIC4C data with NCCID data will be performed using hashed NHS numbers, thus no identifiers will flow to link the data.

The PHOSP study led by the University of Leicester links the data on the basis of consent.

The CCP-Cancer study has transitioned and will provide data to ISARIC under its own separate support (21/CAG/0117). This outcome had a condition of support that ISARIC is supported.

Data from the COG-UK HOCI study, flowing from Public Health England (now UKHSA) to the Scottish National Safe Haven, will be linked by NHS number to ISARIC data, but the data will be anonymised prior to expiry of the COPI Notice, thus support is not required for this. The applicants note that revisions will not need to be made to the study design, as the role previously fulfilled by PHE will be fulfilled by UKHSA. The new role of UKHSA will be reflected in future Protocol revisions and collaboration agreements.

The CAG wishes to make clear that 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.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicants cite the potential size of the cohort as the reason for not seeking consent. The majority of participants will also have been discharged from hospital

and the study team will not be able to contact patients to seek consent. It would also not be feasible for the NHS site staff to consent patients, particularly during the pandemic. Also, approximately 25% of patients will have died since their hospital admission.

Note that the study also contains two consented cohorts of patients, but it is not feasible for this cohort.

The CAG accepted these justifications.

- Use of anonymised/pseudonymised data

NHS number is needed to link routine clinical data collected as part of the CCP-UK study with data held by NHS number and ICNARC. Hence, the data cannot be provided in a pseudonymised way.

The CAG accepted this explanation.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A patient notification strategy has not currently been devised for this application. The applicants believe it is impractical, given that most patient admissions for COVID-19 are for those with severe acute disease; however, if necessary, a physical poster/digital pamphlet could be made, to be circulated to all of the sites in the study via the NIHR Clinical Research Network, to be included in the general research information where this is provided in admission packs.

Aside from patient notification materials, the applicants state that a privacy notice will be made available on the study website. This details how patients' personal data will be collected, used and stored.

The CAG did not consider the notification strategy to be suitably robust. It was unlikely that the cohort would read any of the notification materials, if they were presented in the format proposed.

The CAG would like to see a specific notification strategy rolled out online. The CAG request that a more specific and comprehensive notification strategy be put in place, so that the cohort would be more effectively informed about the study.

The study team has indicated that it does not wish to continue to apply local opt outs, nor to apply the national data opt-out, as the opt-outs may cause bias. For example, it may be that we would find certain geographical areas would be under-represented, or that the figures at comparative timepoints would generally look to be improving, when this may not be the case but instead is due to a reduction in the data available for collection. This would therefore impact the research findings and reporting, and thus in turn may impact local and/or national guidance and/or policy decisions.

The privacy notice is included on the study website - isaric4c.net/privacy. This advises patients that they could withdraw their data and provides email and telephone contacts for the study sponsor as a form of local opt out.

The CAG felt that, despite these justifications, the National Data Opt-Out and a local opt out should be applied. The privacy notice should be amended to be clear about both opt-out mechanisms and how people could apply them. The privacy notice should be available, not only on the ISARIC website, but the websites of the participating Trusts and that of the overarching organisation for the application i.e. the University of Oxford.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants are planning patient and public involvement through a planned survey, a copy of which is provided. Whilst the results are not yet available, the survey is expected to be completed prior to the COPI notice expiring.

A review of the survey indicates that the study and planned uses of identifiable data without consent are well described and provides participants the opportunity to provide their views on the use of this data, as well as in a wider context.

The CAG commends the applicants on the level of PPI that is planned. The CAG would like the PPI to be conducted within 2 months of the issue of this letter, with the outputs being provided to the CAG in response.

Exit strategy

Identifiable data will be stored only at the point of collection and used for linkage. Identifiers will be removed as soon as the data linkage has been made. Linkage is expected to be required until at least 2023, but possibly longer.

The original research data will be archived at Oxford, Edinburgh and Liverpool using local archiving services. The data will be stored in an encrypted format. The data will be pseudonymised, hashing the NHS numbers and identifiers, and storing the data for this securely.

Anonymised and de-identified research data will be stored on managed computer systems in Oxford University, Imperial College, London, the Wellcome Trust Sanger Institute, the Edinburgh Parallel Computing Centre, the Roslin Institute, and University of Liverpool. Critical data will be stored in encrypted form in a stable storage format (eg DVDs), with the passwords recorded on paper in securely held site files.

The applicants advised that data collected for the study will be retained, as it will be of potential value in the future, should similar outbreaks of infectious disease occur. The applicants therefore seek support to retain the data indefinitely in the Edinburgh Data Safe Haven. This data will contain minimal patient identifiers, such as date of birth, ethnicity, NHS/CHI number and postcode.

The CAG agreed that the data could be retained for 5 years in the first instance, with any subsequent extension having to be justified.

The CAG did not consider the identifiers being retained to be ‘minimal’ and therefore requested 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.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

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.

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

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

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.

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

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

7. To 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.

Specific conditions of support

The following sets out the specific conditions of support.

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

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

3. 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 participating Trusts, NHS Digital, and ICNARC is in place once support under Regulation 5 is active.** See below for further details.

4. Resubmitted New Applications – Research

a. 21/CAG/0177 - RAPID2: Randomised trial of clinical and cost effectiveness of Administration of Prehospital

Context

Purpose of application

This application from Swansea University set out the purpose of medical research that seeks to test the safety, clinical effectiveness and cost-effectiveness of paramedics providing Fascia Iliaca Compartment Block (FICB) as pain relief to patients with suspected hip fracture in the pre-hospital environment.

Hip fractures are a common injury for elderly people. Pain relief given before the patient reaches hospital is often inadequate and causes side effects which may slow down recovery. The applicants have conducted a small study to test whether a local anaesthetic injection into the hip area, a treatment called Fascia Iliaca Compartment Block (FICB), given by paramedics at the scene of injury is safe and acceptable. The results concluded that a full trial is feasible.

The applicants will conduct a randomised controlled trial to assess whether FICB is a safe, effective and cost-effective treatment. The research will take place at four research sites in England and Wales. Each site will be comprised of two NHS organisations; an ambulance service and a receiving hospital. Patients will be allocated to receive either FICB or a usual treatment (often morphine) at a ratio of 1:1. Patients in both arms of the trial will still receive Entonox, paracetamol and anti-sickness tablets, as needed. Patients will be initially recruited into the study under the emergency provisions of the Mental Capacity Act. An NHS researcher (paramedic or nurse) will approach the patient within ten days of their attendance by paramedics to discuss the

trial. All patients will be included in anonymised follow up using routinely collected data, unless they dissent from this. Patients will be asked whether they would be willing to take part in questionnaires for the study. If so, they will complete a consent form and be sent two questionnaires - one at one month after the 999 call, and one at four months after the 999 call. Confidential patient information will be uploaded by the participating trusts to the researchers at Swansea University via REDCap. Confidential patient information will then be disclosed from the University of Swansea to NHS Digital and Digital Health and Care Wales for linkage to routine health datasets. A pseudonymised dataset will then be disclosed from NHS Digital to the SAIL Gateway. A pseudonymised dataset will be disclosed from Digital Health and Care Wales to the SAIL Databank for linkage to routine healthcare data and then to the SAIL Gateway.

Patients will be initially recruited into the study under the emergency provisions of the Mental Capacity Act. Support is sought as, while the applicants anticipate that the majority of patients will be consented, some may be discharged from hospital before consent can be obtained. Therefore, the applicants are seeking support to include these patients and to conduct the data linkages to NHS Digital and Digital Health and Care Wales.

A recommendation for class 1, 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 are treated for a suspected hip fracture in a pre-hospital setting. The applicants anticipate that 1404 patients will be recruited, 702 in the control arm and 702 in the intervention arm.
Data sources	3. Confidential patient information from patient records in the following trusts, health boards and ambulance services: a. East of England Ambulance Service,

	b. South East Coast Ambulance Service, c. South Western Ambulance Service, d. Welsh Ambulance Service NHS Trust, e. Princess Royal Hospital, University Hospitals Sussex NHS Foundation Trust, f. Royal Surrey NHS Foundation Trust, g. Ashford and St Peter's Hospitals NHS Foundation Trust, h. Royal Devon and Exeter NHS Foundation Trust i. Swansea Bay University Health Boards, j. James Paget University Hospitals NHS Foundation Trust 4. Patient-reported data: a. pain scores (taken by paramedic before randomisation and at by nurse at arrival at ED); b. One month questionnaire, c. Four month questionnaire. 5. Linked routine data provided by NHS Digital from the following datasets: a. Civil Registrations – Deaths b. Emergency Care Dataset c. HES: Civil Registration (Deaths) Bridge d. Hospital Episode Statistics Admitted Patient Care ~~e.~~ Hospital Episode Statistics Critical Care 6. Linked routine data provided by the SAIL Databank from the following datasets: a. Annual District Death Extract b. Critical Care Dataset c. Emergency Department Dataset d. Patient Episode Database for Wales e. Welsh Demographics Service
Identifiers required for linkage purposes	4. Name 5. NHS number 6. Date of birth 7. Postcode – unit level

Identifiers required for analysis purposes	6. Date of birth 7. Date of death 8. Deprivation scoring 9. Gender 10. Ethnicity

Confidentiality Advisory Group advice
The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicants advised that it is not appropriate to seek consent from patients who are in pain or shock. In their initial application, the applicants had advised that patients would initially be recruited under the emergency provisions of the Mental Capacity Act. Consent will be sought from patients by a trained NHS researcher within approximately 10 working days of the patient's injury. The CAG noted that it was not appropriate to recruit patients under s251 if they refused consent. Any patients who were approached and did not consent needed to be excluded.

In the Deferred Outcome letter, the CAG had asked if it was possible to approach patients sooner in their hospital stay, noting that many patients would be discharged before 10 working days.

The applicants advised that they would contact patients as early as possible during their hospital stay. However, the RAPID1 feasibility trial showed that around 20% of patients are likely to be discharged straight from the ED and not admitted to a ward. This 20% will likely include patients who did not have a hip facture and the applicants know from

RAPID1 that this group of patients will be far more challenging to reach for consent to the trial compared with those remaining in hospital.

If this group of patients were comparable to those more likely to be consented, then their exclusion would be less of a concern. However, most within this group will not have had a hip fracture, but may have been given the FICB anaesthetic because they were suspected of having one. The applicants noted the importance of capturing the benefits and risks for this cohort as the applicants seek to understand the effects of the intervention across the full range of patients in this pragmatic trial. To avoid potential selection bias, the applicants would like to include those that cannot be reached for consent in the routine linked data follow up.

- Use of anonymised/pseudonymised data

The applicants require access to confidential patient information in order to conduct the linkage to NHS Digital and the SAIL Databank and/or Digital Health and Care Wales.

Justification of identifiers

In the Deferred Outcome letter, the applicants had been asked to clarify why patients' date of birth and date of death were needed and whether alternatives, such as month and year of birth or death, or time from injury to death, could be used instead.

The applicants agreed that month and year of birth is a suitable alternative to full date of birth. However, there was no reasonable alternative to collecting date of death. While the number of days from injury to death will be reported in all study outputs, date of death will be required to calculate this. Dates of death will be collected from two sources; NHS Digital mortality data, who do not provide the option to request time from injury to death, only date of death, and from sites. Sites report deaths as part of serious adverse event monitoring. While time to death could be reported, this would not be standard practice and would create additional work for the member of staff completing the serious adverse event report. The applicants also noted that this would create a source of potential error.

It is also noted that, as the study dataset will contain the date of injury, collecting time-to-death is not meaningfully different to collecting date of death directly in terms of confidentiality. Date of death will not appear in any study outputs.

The CAG noted the above information and agreed that, while date of birth could be converted, full dates of death were required.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants noted that the participant information pack will explain how patients can dissent from use of their data. However, this applies to the patients approached for consent, who are outside the scope of support. The National Data Opt-Out would be applied

In their initial application, the applicants provided a combined Patient Privacy Notice and Notification. The applicants advised that they were collaborating with their PPI and communications sub-group members to create a separate Patient Notification document and a project specific dissent mechanism

In the resubmission, the applicants provided a revised patient notification. A project specific dissent mechanism had been created. Details on how to dissent were provided within the patient information pack for those approached for consent. The study will also be publicised by the study team and by each participating ambulance service through their website and social media channels.

The applicants provided the patient information sheet, which incorporates consent and dissent forms. Telephone and email contacts were provided. Postal addresses for the Trial Manager and Chief Investigator are also given, should patients have queries.

The patient information sheet advised that it is not possible for data for patients who opt-out to be removed from information already gathered. The CAG was unclear why the data could not be removed but noted that this may be because the data had been de-identified. Members noted that the wording used appeared to be taken from the HRA standard GDPR transparency wording and agreed that the current wording could remain unchanged.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

A member of the Service Users for Primary and Emergency Care Research (SUPER) Group was active in all aspects of bid development, attended Research Development Group meetings, and had the opportunity to comment on all aspects of study design. The members was named as a co-applicant and remains a member of RAPID2's Trial Management Group (TMG). A second PPI member joined the TMG. Both PPI members have participated in discussions on the study's methodological approach, and support the principles outlined in this application. PPI members have helped to shape patient facing materials including information sheets and notifications. The PPI members of the Trial Management Group and the qualitative analysis sub-group will be offered the opportunity to contribute to future papers and be named as authors if they do so.

Patient and Public Involvement (PPI) contributors will continue their roles on the quarterly Trial Management Group, and the six-monthly Trial Steering Group. The PPI members will also report back to the SUPER group (meeting quarterly), as the study is an adopted study for the group. PPI members are and will continue to be involved in the study communications sub-group which plans and reviews study communications across stakeholder groups.

In response to the CAG comments on the Deferred Outcome letter, the applicants have further consulted the PPI trial management group members on the use of confidential patient information without consent. Feedback was fully supportive of this approach; recognising the importance of including outcome data for those unable to be reached.

Exit strategy

The applicants advised that confidential patient data will only be held at sites, and deleted within 1 year after data collection concludes.

All data transferred to Swansea University will be pseudonymised, with patients known only by a study ID. Only participating NHS sites will be able to link these study IDs to named individuals. These lists will be deleted as soon as possible in line with Good Clinical Practice and the GDPR.

NHS Digital and Digital Health and Care Wales will follow their standard operating procedures for retention of data.

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 standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 05 August 2021.**

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 SAIL Databank (within University of Swansea) and NHS Digital were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 08 December 2021).

   The Caldicott: Principles into Practice (CPiP) for Digital Health and Care Wales was confirmed on 05 October 2021.

5. New applications–Research

a. 21/CAG/0169 - DECLINE: Decisions against curative treatment for lung cancer in eligible patients

Context

Purpose of application

This application from the University of Nottingham set out the purpose of medical research that aims to identify perceived barriers to curative treatment for patients with early stage lung cancer in the East Midlands Cancer Care Network, and to identify reversible factors that can be used to improve treatment rates and hence outcomes for patients with lung cancer.

One fifth of people eligible for curative treatment of their lung cancer, don't receive that treatment. In a third of these cases, it is patient choice to refuse surgery, however the reasons why are unknown. This study will investigate the barriers experienced by both patients and clinicians treating lung cancer patients. The study will examine how to

ensure more people decide to have the best possible treatment. Applicants hope that information gleaned from this study can be used to improve local services in the future.

Applicants will undertake consented interviews with both patients and clinicians. This element of the study does not require 's251' support. Additionally, analysis will be undertaken on a database. Part of the creation of this database does require 's251' support. The database will be generated from local records by the direct care team at 4 Trusts, and will include data for all people aged 18 or older and diagnosed with lung cancer between January 2016 and December 2019. This element does not require support. Each patient will be given a unique identifier, which is linked to the NHS number. The key will be retained by direct care team at each Trust. At this stage the database will contain demographics, information about the patients lung cancer, and will include date of birth and date of death as direct identifiers. Researchers from the University of Nottingham will go to each of the 4 Trusts, and will modify the date of birth, date of death, and date of diagnosis to; age at diagnosis, survival time in days, and months and year of diagnosis. This element requires support, as the researchers are not considered direct care team. The database is now pseudonymised for analysis, and this will be disclosed to the University of Nottingham. In cases where patients do not receive treatment but guidelines would have recommended it, and a reason cannot be identified from the information already collected, members of the research team will visit the local hospital to review the patients' records, looking for a reason why treatment was not given. Applicants assume this may be around 150 records in total. The researcher would have access to clinical records pertaining to the diagnosis. Some of the Trusts have electronic medical records and one uses paper notes. No confidential patient information will leave the Trusts.

A recommendation for class 1, 2, 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	For database: All people aged 18 or older and diagnosed with lung cancer between January 2016 and December 2019, at participating trusts (approximately 5000 patients)

	For case note review: Any patient (in the database) who did not have treatment, and researchers can't find a reason for why this would be the case from the dataset collected (approximately 150 patients)
Data sources	Hospital data from NHS trusts which refer to Nottingham University Hospitals: 1. Nottingham University Hospitals ('s251' support not required, researcher is direct care team) 2. United Lincolnshire Hospitals NHS Trust (comprising Lincoln County and Pilgrim Hospitals), 3. University Hospitals of Derby and Burton NHS Foundation Trust, 4. Sherwood Forest Hospitals NHS Foundation Trust (Kings Mill Hospital)
Identifiers required for purposes of creating the database	Support not required for the identification of the cohort, and initial extraction of the dataset, as is undertaken by direct care team. However the following data items will be viewed by researchers whilst modifying the dataset for analysis: 11. Date of birth 12. Date of death 13. Sector level postcode 14. Gender 15. Ethnicity 16. Pseudo ID For the casenote review (of around 150 patients) researchers will read relevant clinic letters to try and identify the reason for non-adherence to guidance, and will incidentally view confidential patient information whilst undertaking this review. Between the 4 Trusts, there are both electronic and paper records.

Identifiers required for analysis purposes	1. Date of birth modified to age at diagnosis 2. Date of death – modified to survival time in days 3. Sector level postcode 4. Gender 5. Ethnicity 6. Pseudo ID This will be effectively anonymous to the research team.
Additional information	Only direct care team will have access to the key between pseudo ID and NHS number. No support required for the retention of the key. 's251' support not required in Nottingham University Hospitals NHS Trust, as the researcher is considered direct care team at this Trust.

Confidentiality Advisory Group advice
The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The CAG agreed that this application constituted medical research which was in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Minimising flows of identifiable information

The CAG queried whether there was any method of pseudonymising the databases at each of the Trusts so that the researcher would not be required to undertake this

process, reducing the processing of confidential patient information and therefore the amount of 's251' support required. The applicant was asked to confirm that any feasible technical options had been considered, for example, the researcher providing the direct care team with a pre-prepared spreadsheet containing code to automate the pseudonymisation process.

- Feasibility of consent

The applicant reasons that owing to the nature of lung cancer, many patients in the dataset may be deceased and would not be able to offer informed consent. The CAG accepted this justification and did not think consent would be a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is required to be accessed for a short time in order to extract a pseudonymous dataset. It is then also required to be viewed whilst undertaking a review of the medical notes. The CAG agreed that the building of the database, and the medical note review required confidential patient information, and using anonymous information was not a practicable alternative.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A poster has been provided as a patient notification, and this offers an opt out option. The posters will be placed in relevant outpatient waiting rooms. However the applicant has also stated that most of the cohort are expected to have passed away. Mortality rate is 70% in a year, and 90% in 5 years. Therefore this poster will aim to target a very small percentage of patients.

Regarding opt out options, as well as a study specific opt out option offered on the poster, if a patient has registered an opt out against Cancer registration, they will not

be included. Additionally if a patient has opted out of data collection on a local Trust record system they will not be included in the dataset. If a patient has only opted out of the national data opt out, the applicant has stated this will not be applied, as this does not apply to cancer registration, and this is how the clinical team will identify the cohort.

The Members considered that they were broadly content with the poster, but requested some minor changes. The sentence '*All of the information will be anonymised so that it is confidential before it leaves the hospital'* is not accurate and should be altered to state something similar to the following '*All of the information will be anonymised so that it is not identifiable before it leaves the hospital'.*

The explanation of the function of CAG is not accurate. The poster currently states: *'The research team have approval from the Confidentiality Advisory Group under section 251'*. However, as the CAG is not a decision-making group and instead provides recommendations to the decision maker, the Health Research Authority in this case, this statement should be amended to include correct reference to the decision-making element. For example, *'The research team have support from The Health Research Authority, on advice from the Confidentiality Advisory Group, under section 251 of the NHS Act 2006'*

The Group also commented that although the QR code leads you to a description of the study, there is no mention on the poster of what the QR code links to. The applicant should mention on the poster where the QR code links to.

Regarding opt out options, the CAG were content with all the options currently used. However they considered the statement surrounding why the National Data Opt Out would not be applied to be irrelevant, as the purposes of this data collection was for research rather than for cancer registration. The CAG considered the National Data Opt Out should be applied to this dataset. However it was noted that the Trust specific opt outs would be applied, and it was queried whether or not this was actually already linked to the national data opt out.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicant states that Patient and Public Involvement was sought during the inception of this research project, and funding was provided by a patient facing lung cancer charity (Roy Castle Lung Cancer Foundation) following review by their team, which included a review by lay people. They supported the proposed methodology. An experienced lung cancer advocate with lived experience has also provided support for

the study. All lay people reviewing were supportive of the use of confidential patient information without consent.

The Group noted that it appeared only one patient outside of the funder had provided an opinion regarding the use of confidential patient information without consent, and considered that the feedback provided was not very specific. It was felt that the applicant should undertake further Patient and Public Involvement with a number of additional cancer patients who are distinct from the funder, to ensure the use of confidential patient information without consent is acceptable to patients and the public.

Exit strategy

The duration of study is expected to be 24 months, however the 2 elements that require support may finish earlier: The date of death and date of birth will be removed from the database, approximately 6 months after the study begins, but is limited by when the data collection has occurred. It will be undertaken as soon as is practicable after the dataset has been collated by local direct clinicians. Support then no longer required for this element, and the dataset will be effectively anonymous for analysis. Applicants anticipate researchers will have completed the case note review of approximately 150 patients at the 4 Trusts within approximately 3 months from when the pseudonymised dataset has been disclosed to researchers. Applicants judge this to therefore be approximately 9 months from when the study begins. Support will no longer be required once this element of the study has been undertaken. The Committee were content with the exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please confirm if the feasibility of automating the pseudonymisation to allow direct care team to manage the process, and reduce the amount of ‘s251’

support required has been considered, and provide justification if this is not a practicable alternative.

2. Please provide an updated poster which addresses the rectifications requested in this letter. Namely altering the word confidential, altering the description of CAG, and describing the QR code.

3. Please clarify if the Trust specific opt out will include the national data opt out, otherwise please confirm that the national data opt out will be applied.

4. Please undertake further Patient and Public Involvement with a number of additional cancer patients who are distinct from the funder, to ensure the use of confidential patient information without consent is acceptable to patients and the public.

5. Please provide a Favourable Opinion from the REC, as per standard condition of support below.

6. Please provide evidence of NHS Digital review of the 20/21 DSPT for United Lincolnshire Hospitals NHS Trust, as per standard condition of support below.

Specific conditions of support

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

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. **Pending:**

   The NHS Digital **20/21** DSPT reviews for **University Hospitals of Derby and Burton NHS Foundation Trust, and Sherwood Forest Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 December 2021)

The NHS Digital **20/21** DSPT review for **United Lincolnshire Hospitals NHS Trust** is pending.

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

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research to describe the incidence of acute lower-respiratory tract infection (aLRTI) in adults who present to primary care, and to estimate the proportion caused by vaccine preventable infections, including Streptococcus pneumoniae, Respiratory Syncytial Virus (RSV) and SARS-CoV-2.

Currently, accurate incidence rates of acute lower-respiratory tract disease (aLRTD) and its disease subsets, such as pneumonia and aLTRI in individuals presenting to primary care are unknown. The applicants seek to measure the true burden of acute respiratory disease due to these pathogens. The applicants will also undertake quality of life measurements to assess the cost-effectiveness of recommending vaccinations. This study will run alongside a sister study, Avon-CAP (Avon Community Acquired Pneumonia study), which is investigating incidence rates of adults hospitalised with community-acquired lower respiratory tract infection in Bristol. This new application will investigate the incidence rates of adults who present to primary care with chest infections. GP practices in Bristol have been selected in order to capture information for patients with different backgrounds, ethnicities and circumstances.

The study is comprised of two parts. A surveillance study will be undertaken in which routinely collected clinical data will be extracted from participating GP practices for patients who meet the eligibility criteria, and a sampling study, in which patients will be asked to complete an enrolment survey and symptom diaries, and provide naso-pharyngeal/oropharyngeal, saliva and urine samples. Participants will be consented into both parts of the study where possible, and the applicants anticipate that most study activities will be undertaken by the direct care team or with patient consent. If a health professional diagnoses an adult patient with an aLRTD, a prompt will appear advising that the patient is eligible for the study. The health professional will be prompted to outline the study, and seek consent for the patient to be sent a text message about the study. The research team will also follow-up with a phone call to explain more about the study. ‘s251’ support is not required for this process.

Additionally, some patients will be offered an initial screening appointment with a research nurse or research practitioner, however they will have consented to this appointment offered by the direct care team in additional to usual clinical care, and 's251' support is not required for this method of identification.

A research nurse or research practitioner, who is not part of the direct care team, will additionally access patient records to screen patients for eligibility and approach for consent, in order to ensure all eligible patients are approached. 's251 support is required for this element'. An out of hours provider, Brisdoc, does not have capacity to screen for eligibility, and therefore the research staff at GP practices will also screen clinical out of hours letters each day at the GP practices, in order to identify eligible patients who were seen by Brisdoc.

Any patient who has passed away, or who the research team is unable to contact by phone, will not be offered the chance to consent, as it has not been possible. These patients will be included in the surveillance study using 's251'. These patients are not defined as non-responders, as they will not have been supplied information in the post regarding being asked for consent.

Data for the surveillance study will be processed and transferred to the University of Bristol central database on a monthly basis. Identifiable data fields will be removed from the database and transferred to a separate database with restricted access. Senior research staff will use this database to undertake any necessary analysis or processing, for example identifying individuals occurring more than once in the database. Pseudonymised data will then be transferred to a central University of Bristol database, which will therefore combine the pseudonymised data from each participating NHS Trust (AVON CAP). This pseudonymised data will be processed and analysed.

A recommendation for class 1, 2, 3, 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	Adults presenting to participating GP practices in Bristol (including out of hours provider Brisdoc) with acute lower respiratory tract disease, including pneumonia, lower respiratory tract infection and heart failure

	Maximum of 4000 patients, however ‘s251’ support will not extend to those instances where the direct care team have screened and approached the patient.
Data sources	7. Electronic records, including out of hours discharge letters from participating GP practices, a. Courtside Surgery b. Tyntesfield Medical Group c. Concord Medical Centre d. Wellspring Surgery e. Montpellier Health Centre f. Pioneer Medical Group
Identifiers required for identifying eligibility, and approaching for consent purposes	8. Name 9. NHS number 10. GP registration 11. Date of birth 12. Date of death 13. Postcode – sector level 14. Phone number
Identifiers required for analysis purposes	17. pseudo ID 18. date of birth – modified for analysis (by University) 19. Date of death – modified for analysis (in NHS IT domain prior to University) 20. gender 21. Ethnicity 22. Sector level postcode – modified to deprivation score Therefore pseudonymous for analysis
Additional information	Confidential patient information will be retained in a surveillance database at University of Bristol, held separately from the pseudonymised database for analysis, linked to the pseudo ID. This includes NHS number, sector level postcode, and date of birth. Therefore ‘s251’ support required for this element. Confidential patient information regarding the surveillance study will be sent monthly to University of Bristol from research nurses at participating GP practices

Confidentiality Advisory Group advice
The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The Members agreed that this application had a clear medical purpose which was in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Minimising flows of identifiable information

The group referred to the role of Pfizer and understood from the applicants that Pfizer will be provided data to undertake analyses. Members requested confirmation from the applicants that no identifiable patient information will be shared with Pfizer. The applicant is therefore requested to provide a list of which data items will be shared with Pfizer, for reassurance that this is not an identifiable dataset.

- Feasibility of consent

The applicant reasoned that it is not possible to consent patients for the breach regarding researchers screening for eligibility and approaching for consent, and consent will be sought at the earliest opportunity. Consent will be taken where possible for both the surveillance study and the sampling study, however there may be people who have passed away or who the research team are unable to reach by phone. These patients will be included in the surveillance study. To ensure that there is no bias of data or inaccuracy in disease incidence and severity calculations, it is necessary to undertake this research in all eligible individuals. The CAG accepted the justifications provided, and also commended the applicant on making every effort to utilise the direct care team where possible.

- Use of anonymised/pseudonymised data

Confidential patient information is required for identification of correct patient. Confidential patient information is also required in surveillance study arm for de-duplication and linking to AVON-CAP. The Members were content that using anonymous information was not a practicable alternative to the study design presented.

However, the CAG requested clarification regarding what being 'logged and counted' meant regarding patients who opted out. It seems no confidential patient information would be recorded outside of the direct care team for the purposes of being 'logged and counted', however, the Members request that this is confirmed, as it is considered that this could be undertaken without recording confidential patient information.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicant has provided a poster for participating GPs, and a poster for Brisdoc, the out of hours provider. The posters include an opt out option, and a link to the website. A summary website text for GP practices has been provided, and the AVON CAP GP2 study website text has been provided.

The patient information sheet (PIS), consultee information sheet and consent form are provided to the patient after the breach has occurred. After patients read the PIS they have the option to consent or decline. If a patient declines consent, their data will not be used. The CAG would like to remind the applicant that 's251' support does not cover those who decline, and moreover does not cover those who are sent the information sheet, but do not respond, these would have to be considered non-responders, which 's251' support cannot cover; managing-non-response-guidance-v1-2_Aplc9nj.pdf.

The opt out options provided are both via the posters, the websites, and the application of the national data opt out, or initially via the direct care team, if the patient does not wish to be contacted by a researcher. The CAG were content with the opt out methods provided.

In general, the Members considered the notification methods provided to be excellent. They requested some minor alterations to the posters. At the top of both posters there is a sentence stating '*The research team will access the health care records..'.* The CAG requested the addition of 'GP' so that the sentence reads '*The research team will access the GP health care records'.* They also mentioned that the Pfizer logo was not on the poster, and queried if this might be appropriate as they are the funder. The Members also queried if the opt out mechanism could be made more prominent.

In addition to the above, the Members considered that the posters should mention the legal basis under common law being relied upon (Regulation 5 of the Health Service (COPI) Regulations 2002) for the researchers to access the data.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants have set up an AvonCAP GP2 study Patient and Public Involvement advisory group with 14 members. Five Patient and Public Involvement group meetings have been conducted involving the 14 contributors between January and August 2021, with unanimously positive support for the study and the applicants have made changes accordingly. Additionally, a total of 63 individuals completed a Patient and Public Involvement and clinician survey: 39 patients or patients' relatives, and 24 clinicians. All survey participants listened to the researchers explaining the study prior to completing the questionnaire. Almost all (87.1%) participants agreed it was acceptable for researchers to access these data with consent of the individual. The applicant has presented extensive Patient and Public Involvement feedback in a separate document, which does appear to show the acceptability of this use of confidential patient information without consent.

The Members commended the applicant on the excellent Patient and Public Involvement undertaken. The CAG were especially impressed with the set up of the advisory group, the amount of meetings undertaken, and the way the applicant had made suggested changes after listening to patients views.

Exit strategy

The exit strategy for most of the participants will be consent. The study will last 18 months from autumn/winter 2021 with recruitment ending in August 2023. Support therefore no longer required for researchers to screen for eligibility and approach for consent after this point.

Following data linkage and processing of the data, NHS number and date of birth will be deleted from Bristol University database. Applicants will do this within two years of the non-consented study arm ending, and therefore 's251' support required until August 2025. The Members were content with this exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further action would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please provide the evidence requested regarding the one request for further information, within one month.

Request for further information

1. Please provide evidence of NHS Digital review of the 20/21 DSPT for NHS Bristol, North Somerset & South Gloucestershire CCG.

Specific conditions of support

The following sets out the specific conditions of support.

1. Please provide clarification regarding what being 'logged and counted' means regarding patients who opted out. Is any confidential patient information recorded without consent, outside of the direct care team? Please provide a response within one month of final support being provided.

2. Please provide a list of data items disclosed to Pfizer, within one month of final support being provided.

3. Please provide updated posters, as per the guidance above, including the addition of 'GP', the Pfizer logo if appropriate, make the opt out option more prominent, and include the legal basis under common law to access the data. Please provide within one month of final support being provided.

4. Favourable opinion from a Research Ethics Committee. **Confirmed 01 December 2021**

5. 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. **Pending:**

   The NHS Digital **20/21** DSPT review for **University of Bristol - Bristol Medical School (EE133799-BRMS)** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 15 December 2021).

   The NHS Digital **20/21** DSPT review for **NHS Bristol, North Somerset & South Gloucestershire CCG** (to cover the 6 participating GPs) is pending.

6. Minutes of the meeting held on 04 November 2021

The minutes of the meeting held on **04 November 2021** were not reviewed as an outcome is pending.

7. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
_____	_____
Signed – Confidentiality Advice Team	Date
_____	_____