Minutes of the meeting of the Confidentiality Advisory Group

8th September 2022 via Zoom

Present:

Name	**Role**
Dr Murat Soncul	CAG Alternate Vice Chair
Professor William Bernal	CAG Alternate Vice Chair
Dr Sandra Duggan	CAG Member
Mr David Evans	CAG Member
Dr Rachel Knowles	CAG Member
Ms Rose Payne	CAG Member
Mr Dan Roulstone	CAG Member (until discussion of item 3b)
Mr Umar Sabat	CAG Member (until discussion of item 3b)

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr Will Lyse	HRA Approvals Administrator
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
Barbara Molony-Oates	Public involvement Manager (Observer)
Steve Tebbutt	Company Secretary (Observer)

1. Introduction, apologies, and declarations of interest

CAG Vice Chair Dr Patrick Coyle gave apologies.

Mr David Evans announced a potential conflict of interest with item 4a (application 22/CAG/0126). However, after discussion with the Chair it was concluded not to be a conflict 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 **14 July 2022** meeting applications

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **14 July 2022** meeting applications.

3. Amendment

a. 18/CAG/0038 - A randomised controlled trial to evaluate invitation to community-based low dose computed tomography (LDCT) screening for lung cancer versus usual care in a targeted population at risk

Amendment request

This study from the Leeds Teaching Hospitals NHS Trust was supported in April 2018, and aims to test targeted Low Dose Computed Tomography (LDCT) scans screening in community settings concentrating on deprived areas of Leeds. The intention was to randomise 55-80 year old smokers or ex-smokers to intervention or usual care groups prior to approach. The intervention group were invited to an assessment for a Lung Health Check (including LDCT screening for high-risk people) framed as a pilot health service. The applicants intended to compare outcomes between the invited group and a usual care group, who weren't invited to take part or know that they were in a research study. By comparing outcomes with a control population, the true benefits (of reducing number of late stage cancers, and therefore lives saved) and possible harms (of over-diagnosis) of introducing screening in the UK will be assessed. It was noted by CAG that this study is designed in the style of a screening programme, and that consent and an introduction to the research study does not come up until the patient turns up for the screening scan.

Multiple amendments have been supported, but the most relevant is an amendment supported in 2021 to allow applicants to re-contact by phone, 1000 high risk individuals who had stopped responding, but had initially responded.

This amendment sought support for 3 changes to 's251' support;

- **Change 1**: Identification of newly-eligible participants for screening
- **Change 2**: Pathway navigation (PN) for repeat non-responders
- **Change 3**: Recontacting people disengaging from screening programme using patient navigation (PN)

- This amendment also formally confirms an administrative change - the data processor name at University of Leeds has changed from 'University of Leeds-IRC' to 'University of Leeds-LASER', and this is reflected in the name of the DSPT required.

Change 1

Change 1 is the introduction of re-screening for individuals who may have become eligible since the initial screening for eligibility. Eligibility for lung screening relates largely to age and smoking history and thus changes over time. Those people who may have become newly-eligible would be contacted by telephone to undertake a repeat telephone triage assessment. If this confirmed eligibility, then an appointment would be made to attend the mobile screening unit. The research nature of the YLST would then be explained at this appointment alongside an informed consent conversation.

Change 2

Change 2 is requested as only 50% of people receiving a postal invitation asking them to make contact with a Lung Health Check service for risk assessment took up that offer. Furthermore, uptake was skewed towards those from more affluent areas, and towards those people who had quit smoking. Applicants propose to randomise individuals who ignored a previous invitation for lung screening, into a PN sub-study. Those allocated the intervention arm would receive an advanced notification letter three weeks before their scheduled telephone appointment time. This is because provision of a scheduled appointment was shown to increase participation in other screening programmes. This notification would include dissent information and an opt-out telephone number should participants not wish to receive a subsequent phone call. At the pre-arranged time, a Pathway Navigator would contact the participant to discuss lung screening. The aim of this is to understand the barriers to screening and to try and help individuals to attend. The PN intervention will be tested using a service demonstration design which frames the intervention as usual care to those receiving it. This means participants will be unaware of the research nature of the Yorkshire Lung Screening Trial until they attend for a Lung Health Check appointment at which fully informed consent will be collected for their participation.

The applicants confirmed they have identified 14,960 people who will be eligible for randomisation as part of the PN study. The control arm would receive a further written invitation to contact the team for lung cancer risk assessment. This written invitation would be the same as they received in the baseline round of screening and mimics the recall of existing screening programmes. There are no plans to collect any additional information regarding these participants. The data that was extracted at the start of the study remains on file, and will be used to describe differences between those who participate in the PN study and those who do not.

The applicants confirmed that none of the 1000 individuals who were contacted as part of the 2021 amendment would be re-contacted for any part of this amendment, as they are a different sub-group of individuals.

The applicants also confirmed that the following groups of people will not be contacted for the purposes of this amendment;

1) People who had requested no further contact from the Lung Health Check team
2) People in whom screening was previously considered not appropriate for medical reasons (dementia, frailty, significant comorbidity making screening inappropriate)
3) People who were deemed unable to consent to the study
4) People who were unable to proceed with screening (e.g. unable to lie flat for the scan)

The justification provided for this amendment in queries answered prior to the meeting, is that it is in the public benefit - lung cancer screening has been shown to reduce lung cancer deaths, and the UK National Screening Committee is considering whether to introduce a nationwide screening programme currently. Participation in lung cancer screening remains lower than other established screening programmes, and data from the YLST indicates that those from more deprived communities were 42% less likely to respond to participate in lung cancer screening, and those people who continue to smoke are 56% less likely to take part than comparator groups. Both deprivation and continued smoking are major risk factors for lung cancer, thus the people at highest risk of this disease appear less able or inclined to participate in screening. There is therefore an urgent need to address barriers to participation in these populations in order to maximise the lives saved by lung cancer screening and ensure equitable access to services in those most at risk of lung cancer. By increasing participation in screening from individuals from deprived populations and who continue to smoke, will offer the possibility of preventing lung cancer deaths through earlier detection for the population who are most at risk of this disease. This amendment aims to address and overcome the inequities that appear to exist in current participation in lung cancer screening, and therefore to maximise the health benefits of screening for more deprived populations. Applicants hope this will help to reduce the significant health inequalities that persist in the UK population and provide strategies for equitable implementation of any future national lung cancer screening programme.

The applicants also reasoned that the design of YLST has always aimed to mimic a possible future nationwide screening programme (and therefore to gain information to inform what that programme might look like). This randomised study seeks to gather evidence to see if PN is a worthwhile and cost-effective intervention to add to a possible future nationwide programme.

The applicant has provided specific justification and detail relating to contacting non-responders for this purpose;

1. Prior invitation letters have always included a clear method for individuals to dissent from the use of their data and to opt-out of any further contact. The small

minority who have dissented will not be contacted and are excluded from the repeat non-responder group.

2. Prior invitation letters have not sought explicit consent at the invitation stage. Consent is sought during the subsequent face-to-face Lung Health Check appointment should they choose to attend. The letters simply ask individuals to telephone to begin the process of eligibility assessment and appointment booking. The applicant reasons that those not responding to prior invitations therefore cannot be considered a failing to explicitly consent as they were not asked to do so (in line with guidance:
    3. There are different reasons for non-response beyond informed personal choice, as evidenced by research implicating practical and motivational barriers to participating in lung cancer screening which underpin inequalities in participation.
        a) Prior invitation letters not received/understood. Applicants do not know how many of those who did not respond a) received the postal invitation (e.g., incorrect address, difficulty receiving post at multi-resident address) and b) were able to read or understand the contents (due, for example, to literacy, English language, sight difficulties). The PN intervention will use a timed phone call to support effective contact of individuals and strategies which support comprehension to not only support participation, but also informed consideration of the offer.
        b) Inclined to respond but do not. These individuals may be interested in screening or intended to respond previously but did not. Reasons are wide-ranging with examples ranging from conflicting/competing priorities (eg, work/caring responsibilities) and issues with access (e.g. transport, cost, disability) to procrastination or forgetfulness. In the context of cervical cancer screening, research in England suggests that half of women who have not participated do actually intend to do so and that women from lower socioeconomic backgrounds are more likely to not realise their intention to participate. The PN intervention will use strategies to support access and planning should they personally choose to participate.
        c) Misinformed non-response. These individuals may hold misconceptions about their eligibility for lung cancer screening (e.g. I have smoked too long), their likelihood of benefitting from early detection and the efficacy of treatment (e.g. having known close others die of lung cancer when diagnosed late), may fear being diagnosed at screening or may believe they will be stigmatised due to their tobacco dependence. Research shows these perceptions are more common among those living in areas experiencing socioeconomic deprivation and those who currently smoke. The aim of PN is to help overcome emotional barriers and misconceptions based on deep-rooted personal experience of the disease and offer strategies to support their response and attendance should they personally choose to do so.
        d) Informed non-response. These individuals have made an informed choice not to respond but have not dissented from data use nor further contact. Applicants respect their right to do so but cannot practicably identify which individuals they are in order to remove them from invitation to the third screening round. They may continue not to actively dissent, may not

respond to their invitation to the third screening round (if in the control arm), or decline to participate during a timed phone call (if in the intervention arm). This letter will be sent approximately 2 years after their prior invitation and is routine activity for a NHS service to re-invite the eligible population periodically. If applicants do achieve contact with someone in this group, they will fully respect any choice to decline participation.

4. There is evidence that repeat contact strategies for cancer screening are more effective at engaging those experiencing socioeconomic deprivation (eg, reminders, advance notification).

In addition, the applicants state that they have undertaken a patient and public involvement exercise to understand the acceptability of this observational approach to collecting 'anonymous' data for analysis without seeking individual informed consent.

Change 3

Change 3 is requested to allow the recontacting of people who disengaged from the screening programme by using PN. In YLST, of 7,954 people found to be at high risk of Lung Cancer following telephone triage assessment, 1,304 people did not proceed to screening. Some were appropriately excluded, however, the commonest reason for not attending, was failing to attend on the day (DNA) or contacting to cancel their appointment. Continued participation in screening is essential to achieve the mortality benefits demonstrated in the randomised studies. People with potentially reversible reasons will be contacted by telephone and offered an opportunity to reengage with the Lung Health Check programme should they wish. Change 3 therefore aims to explore reasons for non-attendance/adherence in previously eligible participants. The same PN approach described above will be used to elicit, and where possible overcome, barriers to attendance.

Confidentiality Advisory Group advice

The amendment was considered by the CAG, at a full CAG meeting. The CAG were supportive of change 1, noting that this is reasonable, and is a process that would be likely to happen in a real life screening programme.

The CAG mostly discussed change 2, as this related to contacting non-responders. The Members noted that the justification for change 2 related to addressing health inequalities, and agreed with the applicants assessment that non-responders may not be the same group as those who do respond, and until the applicants understand the barriers, then these individuals won't be invited in a way that is appropriate. The Members noted that the applicant had stated people who were smokers, and from more deprived areas were the individuals less likely to attend, and it is these individuals who are more at risk of lung cancer, and therefore more of need of screening. The Group noted it is important that these individuals are not put at a disadvantage by inappropriate methods of invitation for screening, and this amendment will aid researchers in how to improve the invitation process. This will increase early detection of lung cancers, and

save lives. The Group was therefore convinced of the huge public interest in this amendment, if the characteristics of the non-responders are as described.

The applicants is therefore requested to confirm in writing the points made in the meeting, to confirm evidence that the characteristics of the non-responders are the same as those individuals who are at higher risk of lung cancer, to ensure the amendment is in the public interest.

Members also noted that as the invitations are sent out mirroring a future screening programme, patients may reasonably expect to receive another invitation for screening 2 years on, noting that this methodology was not too intrusive.

The Group noted the applicants reasoning that as these individuals were not explicitly asked to consent in the initial invitation to screening letters, that they could be considered slightly differently than non-responders to a request for explicit consent. The CAG were not necessarily agreed on this specific point, however it was also noted that as no-response to a previous request for explicit consent does not automatically preclude 's251' support, if the purpose of the amendment is distinguishable from the purpose for which 'consent' was previously sought. The CAG were in agreement that the PN element pf change 2 is sufficiently different in purpose from that for which original support was given, as this amendment is to inquire into the potential reasons for non-response. And therefore whether or not explicit consent was sought initially is moot.

Members noted the patient and public involvement undertaken to understand the acceptability of this observational approach to collecting 'anonymous' data for analysis without seeking individual informed consent. However the CAG were not convinced by the statements written as part of the submitted amendment, as this referred to anonymous data, but individuals contact details would be used in order to invite them for screening/PN. The applicant was asked in the meeting to define what patient and public involvement had been undertaken with regards to specifically approaching non-responders. The applicants did not have the details with them in the meeting, but stated that a group of patients and the public had been asked specifically abut this proposal. The applicant is required to provide this evidence in order for the amendment to be supported.

Members would like to be clear that this is not a precedent setting decision, and any similar amendments in the future will be considered on its own merit, on a case-by-case basis. It was felt that this amendment was exceptionally in the public interest, and therefore should be supported, as there is potential for lives to be saved if this amendment goes ahead.

Discussions regarding change 3 required some clarifications from the applicant who attended. The CAG wanted to know whether this was regarding individuals who had only disengaged once, or if this was repeat disengagers? The CAG were supportive of the amendment for those who disengaged once, and also noting that this should not cover any re-contacting of the 1000 individuals previously re-contacted as part of a previous amendment. The applicant confirmed in the meeting that this group is individuals that initially phoned the trial to take part in screening, and had undergone a lung cancer checklist. The applicant confirmed this is a newly disengaged cohort, and

that no repeat disengagers will be contacted. The applicant noted that there is a big percentage of individuals who have consented into the trial but have failed to come back for a follow up, and it is important that these individuals can be re-contacted. The CAG were supportive of change 3, and were reassured by the fact that applicants will not be re-approaching those who have been re-contacted before.

Confidentiality Advisory Group 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 the evidence that shows that the characteristics of the non-responders are the same as those who are at more high risk of lung cancer.

2. Please provide evidence of specific support form patients and the public, surrounding the contacting of non-responders for the purpose of change 2.

3. Please provide the Favourable Opinion of the REC, as per standard condition of support

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

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

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

The NHS Digital **21/22** DSPT reviews for **Leeds Teaching Hospitals NHS Trust, University of Leeds – Laser, CFH Docmail LTD, Reed Wellbeing Ltd, and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked **26 September 2022**)

2. Confirmation of a favourable opinion from a Research Ethics Committee; **Pending**

4. New Applications

a. 22/CAG/0126 - TVS Trusted Research Environment (TRE) Programme

Context

Purpose of application

This application from Oxford University Hospitals NHS Foundation Trust set out the purpose of creating a research database that will collate routinely collected data for all patients routinely treated by the NHS in Thames Valley and Surrey in a secure data environment.

The data collected with be for all patients who receive NHS treatment within the Thames Valley and Surrey (TVS) area. The TVS is comprised of three NHS Integrated Care Systems (ICS); Buckinghamshire, Oxfordshire and Berkshire West, Frimley Health and Care, and Surrey Heartlands. The data will be collected into a Trusted Research Environment (TRE) at Oxford University Hospitals NHS Foundation Trust. A Trusted Research Environment is a controlled digital environment, which can be used to store or analyse sensitive data in a secure fashion. The data collected into the TVS Trusted Research Environment (TRE) Programme database will be used to support translational research, including the development, evaluation and monitoring of new approaches to care delivery.

Patient data will be obtained from shared care records and records from specialist systems and services. Confidential patient information will be transferred from participating NHS organisations to Oxford University Hospitals NHS Foundation Trust. A 'standardised' version of the raw data will be created, where key data items, including NHS numbers, will be held in canonical representations. This 'standardised' version of the data will then be linked, filtered, and transformed to produce a 'research database' version. This version does not contain any direct identifiers as the data pertaining to each patient will be associated with a different 'subject IDs'. The subject IDs will not be shared with researchers.

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

Confidential patient information requested

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

Cohort	1. Electronic patient records held at: a. Buckinghamshire, Oxfordshire and Berkshire West Integrated Care System (BOB ICS) b. Oxford University Hospitals NHS Foundation Trust c. Oxford Health NHS Foundation Trust d. Berkshire Healthcare NHS Foundation Trust e. Royal Berkshire NHS Foundation Trust f. Buckinghamshire Healthcare NHS Trust g. South Central Ambulance Service NHS Foundation Trust h. Frimley Health and Care Integrated Care System (ICS) i. Frimley Health NHS Foundation Trust j. South East Coast Ambulance Service NHS Foundation Trust k. Surrey and Borders NHS Foundation Trust l. Sussex Partnership NHS Foundation Trust m. NHS Frimley CCG n. Surrey Heartlands Health and Care Partnership Integrated Care System (ICS) o. Ashford and St. Peter's NHS Foundation Trust p. Epsom and St Helier University Hospitals NHS Trust q. Royal Surrey County Hospital NHS Foundation Trust r. Surrey and Sussex Healthcare NHS Trust s. NHS Surrey Heartlands CCG Victoria t. Great Western Hospitals NHS Foundation Trust 1. Milton Keynes University Hospital NHS Foundation Trust
Data sources	1. Name 2. NHS number 3. Hospital ID number 4. GP registration

	5. Date of birth 6. Date of death 7. Postcode – unit level
Identifiers required for linkage purposes	1. Initials 2. Full name 3. Address 4. NHS number 5. Hospital ID number 6. GP registration 7. Date of birth 8. Year of birth 9. Date of death 10. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – sector level 2. Gender 3. 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.

Scope

The CAG noted that the database was not solely a research database and requested clarification on its purpose. Furthermore, CAG requested clarification regarding the references to non-research within the application. CAG stated that if this proposal was also for non-research, then the applicant would need to submit a separate non-research application. Due to the lack of clarity over the purpose of the database, the CAG determined that support could not be recommended.

Free Text

The CAG requested more information regarding the free text. Firstly, the CAG requested further details on who would undertake the processing of free text data and how this processing would be managed

The CAG queried whether any patient and public involvement had been undertaken around the specific issue of processing of free text data and, if so, whether feedback from this could be provided. If patient and public involvement had not been undertaken around this issue, the CAG asked that this was done, and feedback provided.

Management of Research Database

The CAG required further detail on how the database would be managed, including the governance structures involved. Members queried whether the applicants had created a Data Access Committee and if so, how it would decide on how requests to access the data would be handled. The CAG also requested details on the proposed membership of the Data Access Committee, such as the planned proportion of lay members to expert members.

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 had advised that four million patients lived in the Thames Valley and Surrey area and that seeking consent from this number of patients was impracticable.

The CAG was content with the justification provided by the applicant that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required so that the data can be checked for accuracy.

Any data collected that cannot be linked to a patient NHS number will be deleted.

Researchers who apply to use the database will also have access to extracts from the database, which will be minimised to meet the needs of each specific project. These extracts will be copied to the trusted research environment and made available only to the researchers working on the specific project.

CAG was content that 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.

The applicants plan to begin a patient notification strategy in September 2022. This will include presenting information online and on social media. Local radio and print media will also be used to promote the study. Posters and leaflets will be displayed in participating NHS organisations. Information will also be presented at research open days and community events.

A patient information leaflet was provided, but not the other notification materials. Email, telephone, and postal contact details were given.

The National Data Opt-Out will be applied. The applicants noted that the TVS TRE programme would not rely upon the National Data Opt-Out for notification or the recording of choices, although any choice recorded for the National Data Opt-Out will be respected

The CAG noted that the Patient Notification did not clearly explain how participants could opt-out from the study. The CAG asked that details on how patients can opt-out were provided

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 TRE is being established by Oxford University Hospitals NHS Foundation Trust in partnership with organisations across the locality, including: the existing TVS local health and care records (LHCR) programme; Thames Valley Cancer Alliance; with two large Biomedical Research Centres (BRCs) funded by the National Institute for Health and Care Research (NIHR); and the Oxford Academic Health Sciences Network (AHSN). All of these organisations have an interest in translational research, and all have existing (and often extensive) engagement and involvement programmes. The applicants will work with them to ensure that the TRE programme is an integral part of their engagement and involvement activity, and will connect to and build upon existing workshops and networks: in particular, those organised by the TVS LHCR and the BRCs.

Although it was noted that Patient and Public Involvement had been conducted, the CAG had not received information and feedback from any specific activity. The CAG requested that the Chief Investigator provide information regarding the Patient and Public Involvement carried out, clarifying the topics of discussion and responses as well as the makeup of the cohort.

Exit strategy

The linked version of the data will be constantly refreshed and retained for the lifetime of the database. It will be deleted as soon as no longer required to produce de-identified data extracts.

CAG was content with the exit strategy.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Health Research Authority recommended that the application was **deferred**.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Further clarification on the purpose of the database is requested. If non-research uses are included, then a separate non-research application will be needed.

2. Further details on who will undertake the processing of free text data and how this processing will be managed are required.

3. Feedback from any patient and public involvement undertaken around the use of free text data needs to be provided. If no patient and public involvement has been undertaken around this specific issue, then it needs to be done and feedback from this provided.

4. Further detail on how access to the database will be managed are required. This needs to include details on governance structures, and the Data Access Committee and the lay representation included

5. The Patient Notification needs to be revised to clearly explain how participants can Opt-Out from the study.

6. Further details on the patient and public involvement carried out need to be provided. This needs to include details on the topic's discussion and the responses, as well as information on the demographics of those consulted.

b. 22/CAG/0112- Randomised trial of the clinical and cost effectiveness of a supraglottic airway device versus intubation during in-hospital cardiac arrest

Context

Purpose of application

This application from the University of the West of England set out the purpose of medical research that seeks to determine the clinical and cost effectiveness of a supraglottic airway device versus tracheal intubation during in-hospital cardiac arrest. In hospital cardiac arrest (IHCA) occurs in approximately 1 in 1000 hospital inpatients. It is a sudden, unpredictable, and life-threatening event and has significant mortality and morbidity. Survival to hospital discharge following resuscitation for IHCA is around 24% in the UK. However, additional data collected for patients who require advanced airway management, such as the insertion of a tracheal tube or a supraglottic airway device, suggests that survival for this patient group is closer to 10%.

Effective cardiopulmonary resuscitation (CPR) is central to achieving good patient outcomes, however chest compressions alone do not provide adequate lung ventilation and effective airway management is essential. A previous trial, AIRWAYS-2, explored use of tracheal intubation versus the i-gel supraglottic airway device in OHCA. This did not detect a significant difference in functional outcome (including mortality) between the two advanced airway management techniques. Since then, updated international resuscitation guidelines support the use of supraglottic airways (SGAs) in settings where intubation success rates are lower. Changes have been made in management of airways when paramedics treat Out of Hospital Cardiac Arrest (OHCA), but not where doctors manage the airways. The applicants seek to determine whether SGAs are superior to tracheal intubation in

situations where intubation success rates are assumed to be high. The applicants will conduct a multi-centre, open-label, pragmatic, individually randomised, parallel group, superiority trial and economic evaluation. Patients will be recruited by NHS clinicians, usually the member of the in-hospital cardiac arrest team who is designated to manage the patient's airway. The clinician will assess patient eligibility. Patients will be randomly allocated, at a ratio of 1:1, to receive either a supraglottic airway device (intervention arm) or tracheal intubation (control arm). The randomisation will be conducted using a phone progressive web application (PWA) which will inform the Warwick CTU that the randomisation has occurred. Patients will initially be recruited under the Mental Capacity Act, as patients will be unconscious when entered into the trial. Consent will be sought from patients who regain capacity. Support is required to include patients who die before consent can be sought. Confidential patient information will be disclosed to the University of Warwick. Individual level patient data will be disclosed to NHS Digital, PEDW and ICNARC for linkages to datasets these organisation hold, and a linked dataset returned to the University of Warwick.

A recommendation for class 1, 2, 3, 4, 5 and 6 support were requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Patients aged 18 years and over who experience an in-hospital cardiac arrest, are attended by the hospital cardiac arrest team and who require resuscitation with advanced airway management. 4190 patients will be included.
Data sources	1. Participant NHS hospital Trusts 2. NCAA (National Cardiac Arrest Audit), held by Intensive Care National Audit and Research Centre (ICNARC) 3. Patient Episode Database for Wales (PEDW), held by NHS Wales Informatics Service (NWIS) 4. Health Data Research UK (HDR UK)

Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode – district level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – district level 4. Gender 5. 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**

Patients will initially be recruited under the Mental Capacity Act, as patients will be unconscious when entered into the trial. Consent will be sought from patients who regain capacity. Support is required to include patients who die before consent can be sought.

The CAG requested clarification on the consent process. Clarification on when consent was sought and whether consent was sought for only those who survived the cardiac arrest was requested.

It was unclear what would be done with confidential patient information collected for patients who survived and were contacted for consent but refused consent. From the information given, it appeared that confidential patient information for these patients would be retained. The CAG requested confirmation that, should a patient who was approached for consent refused, then their confidential patient information would be deleted.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link patient data provided from the hospital trusts to datasets held by NCAA (National Cardiac Arrest Audit), Intensive Care National Audit and Research Centre (ICNARC), Patient Episode Database for Wales (PEDW) and Health Data Research UK (HDR UK).

'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 will be applied. A record of the total number of patients in each arm who were withdrawn for this reason will be kept.

A draft poster was provided, which would be displayed in all recruiting hospitals. The poster contained email, telephone, and a website addresses for opt-out requests. The CAG asked that the poster was revised to provide more information about the study. Online methods and patient notification also needed to be explored and feedback provided to the CAG.

The CAG asked the applicants to consider ways of sign-posting those whose first language was not English to information about the study.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public are 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 involved patient and public representatives when designing the trial. A core Patient and Public Research Advisory Group and members of the PCPIE group (a patient, Carer and Public Involvement and Engagement group based at the Royal College of Anaesthetists) have advised on the study. These groups will be updated on the progress of the trial and their engagement will be sought at all stages of the research. It is anticipated that the core Patient and Public Research Advisory Group will meet at least 12 times during the study, and AIRWAYS-3 will be a standing agenda item with a written report, feedback from the patient and public involvement representatives on the Trial Steering Committee and consideration of specific matters arising as well as trial inclusion. Similarly, PPI will be a standing agenda item at all trial-related management and committee meetings, with dedicated patient and public involvement representation on the Trial Management Group. The core Patient and Public Research Advisory Group has been particularly engaged in issues relating to the conduct of trials in emergency situations where it is not possible to gain prior consent, and associated data collection and management in this and previous cardiac arrest trials. Group members have discussed and approved a statement setting out their views that accompanies this application. The involvement of these contributors will be key in carrying this trial through to completion.

CAG was content with the patient and public involvement conducted.

Exit strategy

Items of confidential patient information will be deleted once the data linkage work is complete. The applicants expect that this will be before the 31 December 2026. The applicants advised that it would be possible to convert patients age and date of birth to less identifiable formats and would do so.

The CAG asked whether the confidential patient information could be de-identified as the project was ongoing, or whether all confidential patient information would be held until 31 December 2026.

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. The CAG request clarification on the Consent process. It was queried at what point consent was sought and whether consent was sought for only those who survived the cardiac arrest. Clarification on the consent process needs to be provided as follows:

    a. Clarify when consent would be sought and whether consent was sought for only those who survived the cardiac arrest.
    b. Confirmation that, should a patient who is approached for consent refuse, then their confidential patient information will be deleted.

2. The poster needs to be revised to provide more information about the study.

3. Methods of promoting the study online need to be explored and feedback provided to the CAG.

4. Methods of sign-posting those whose first language was not English to information about the study need to be explored and feedback provided to the CAG.

5. Clarify whether the confidential patient information can be de-identified as the project is ongoing, or whether all confidential patient information will be held until 31 December 2026.

Specific conditions of support (provisional)

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. **Confirmed 22 July 2022**

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

    The NHS Digital 21/22 DSPT review for**, Intensive Care National Audit and Research Centre (ICNARC)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13/09/2022)

    The NHS Digital 21/22 DSPT reviews **University of the West of England, Health Data Research UK (HDR UK)** were pending NHS Digital review.
    NHS Wales Informatics Service (NWIS) – CPIP in place

c. 22/CAG/0120 - A Retrospective Follow-up of Two Services for High Risk Offenders with Personality Disorder

Context

Purpose of application

This application from the East London NHS Foundation Trust set out the purpose of medical research that seeks to evaluate re-offending and psychosocial wellbeing outcomes after interventions provided by two Offender Personality Disorder (OPD) Pathway programmes.

Personality disorders (PDs) are a group of mental health disorders that are characterised by inflexible, maladaptive patterns of behaviour, emotional expression and cognition. These patterns are long-standing and affect a range of personal and social situations. The Offender Personality Disorder (OPD) Pathway programme is a jointly commissioned initiative between NHS England and Her Majesty's Prison & Probation Service. It encompasses psychologically informed services for offenders who are likely to have a PD. These treatment services are set in prisons, secure hospitals, and community settings, and all aim to reduce repeat offending and improve psychological wellbeing. There is limited evidence that various treatments have a positive impact of recidivism rates and psychological behaviours and behavioural outcomes among personality disordered offenders, however few follow-up studies have been undertaken. The applicants are seeking to examine the long-term psychosocial and reoffending outcomes, and the impact of services on sentence progression, for all men who have passed through two OPD Pathway services since they opened; a Psychologically Informed

Planned Environment (PIPE) at HMP Swaleside and an adapted therapeutic community model run by the Millfields Unit. Data will be gathered from existing service, prison, probation and police records. The results could help to inform the future development and improvement of similar services, in order to improve the availability and effectiveness of services supporting offenders with PD.

Research teams at Millfields Unit and Swaleside will identify suitable patients from their local records. At the Millfields Unit, patient names and dates of birth will be transferred to a password-protected database and assigned unique study IDs. This database, which will include confidential patient information and the unique study IDs will be transferred to HMP Swaleside via encrypted email.

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	All men who have ever been admitted to and discharged from the Millfields Unit between 01 January 2005 – 31 December 2021 or the PIPE at HMP Swaleside between 01 January 2014 – 31 December 2021. For the control group, men who were referred to the PIPE, but not admitted, between 01 January 2014 – 31 January 2019 are eligible for inclusion. 150 patients will be included in the control group. Approximately 80 patients will be recruited from Millfields Unit
Data sources	1. Patient records at the Millfields Unit (East London NHS Trust)
Identifiers required for linkage purposes	1. Name 2. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Prison/hospital security level 4. Accommodation type 5. Gender 6. Occupation 7. 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 requested further clarification on the purpose of the application and whether the study would be used to improve the care of patients, or whether the results would be used to inform how the units are run.

Scope

The CAG requested clarify on the scope of support sought. The remit of s251 applies to confidential patient information, as defined in s251 of the NHS Act 2006. In short, this covers patient information generated in circumstances leading to an obligation of confidence. The CAG was satisfied that data from the Police National Computer, probation records and prison records were outside s251, the remit does extend to prisoner health records, whether these were generated by the NHS or another healthcare organisation providing the care and treatment of prisoners.

The applicants had indicated that patient records at the Millfields Unit were under the scope of support, while records from the Swaleside Unit were outside the scope of support.

The CAG requested that the applicants confirm that the records held by HMP Swaleside that would be processed for this application were not health records.

The applicants had agreed that the National Data Opt-Out would be applied to patient records at Millfields. Patient records would also be checked for evidence of existing dissent to use of their data in research.

If any of the data provided by HMP Swaleside is determined to be confidential patient information, then the National Data Opt-Out will need to be applied to this cohort. A local dissent mechanism, including checking of records for evidence of existing dissent to use of their data in research, will need to be implemented.

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**

In the study protocol, the applicants cited the sample size as a reason for not seeking consent. However, approximately 330 patients would be recruited, which is a relatively small cohort. The applicants had cited a low and potentially biased response rate, which the CAG agreed is a stronger reason for not seeking consent. Former patients may be difficult to locate and unlikely to give informed consent.

CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link patients across several datasets and organisations.

CAG was content that use of 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 notice, (document - Participant information), about the study will be placed on the East London NHS Foundation Trust, Millfields Unit and London Pathways Partnership (LPP) websites. This notice will include details on the purpose of the study, the data used and how it will be stored. Email and postal details were provided for participants who wish to ask further questions or to dissent from data collection. A telephone number for the Swaleside was also included.

In response to suggestions from a focus group with current Millfields patients, information about the study will also be shared with commissioners and will be added to the Millfields Unit microsite once this has been developed.

Any participants who choose to opt-out from data collection will be removed from the study and any research data collected up to that point will also be destroyed. The applicants had agreed that the National Data Opt-Out would be applied to patient records at Millfields. Patient records would also be checked for evidence of existing dissent to use of their data in research.

If any of the data provided by HMP Swaleside is determined to be confidential patient information, then the National Data Opt-Out will need to be applied to this cohort. A local dissent mechanism, including checking of records for evidence of existing dissent to use of their data in research, will need to be implemented.

The CAG noted that not all of the target population would have access to a computer and/or the internet and queried whether posters could be used to promote the study as well as online information. If this approach is not feasible, justification as to why needs to be provided.

The CAG noted that the prison population tended to have a lower reading age than the general population and asked that the patient notification materials were reviewed with help from a Patient and Public Involvement group.

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 CAG asked that the patient notification materials were reviewed with help from a relevant Patient and Public Involvement Group.

Exit strategy

All identifiable data, including confidential patient information, will be pseudonymised at the point of extraction. All participants will be given a unique, numeric study ID. Upon extraction of data from patient records, this information will be allocated to the study IDs so that the final research dataset will not contain identifiable data. The pseudonymised data and identifiers will be held in separate password-protected databases. It is estimated that data collection will be complete within 2.5 years and all data will be pseudonymised by this point. The names used for data linkage will then be destroyed. The applicants advised that precise dates of birth are required so they can be passed on to HMP Swaleside to identify the same participants for follow-up. Once they have been identified in prison/probation systems, dates of birth can be converted to age and dates of birth removed. Since date of death is not needed to be passed on to Swaleside, this can be converted to age at death upon data extraction.

CAG was 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. Provide further clarification on the purpose of the application and whether the study will be used to improve the care of patients, or whether the results will be used to inform how the units are run.

2. The CAG requested that the applicants confirm that the records held by HMP Swaleside that would be processed for this application were not health records.

3. If the data held by HMP Swaleside is confidential patient information and will be processed under s251 support, then confirmation needs to be provided that the National Data Opt-Out will be applied, as well as a local dissent mechanism.

4. Use of posters, as well as online information, needs to be considered. If this approach is not feasible, justification as to why needs to be provided.

5. The wording of the online information and any other patient notification materials, such as posters, need to be reviewed by a relevant Patient and Public Involvement group.

Specific conditions of support (provisional)

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 21/22 DSPT reviews East London NHS Foundation Trust**,** HMP Swaleside (Ministry of Justice), were pending NHS Digital review.

5. Any other Business

No other business was raised. The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	**Date**
Dr. Murat Soncul &	*27/09/2022*
Professor William Bernal, CAG Alternate Vice Chairs	*29/09/2022*

Signed – Confidentiality Advice Team	**Date**
Mr William Lyse, HRA Approvals Administrator	*21/09/2022*