Minutes of the meeting of the Confidentiality Advisory Group

20 January 2022

Held via Zoom

Present:

Name	
Dr Malcolm Booth	CAG member
Ms Sophie Brannan	CAG member
Dr Patrick Coyle	CAG vice-chair
Professor Lorna Fraser	CAG member
Dr Rachel Knowles	CAG member
Ms Rose Payne	CAG member
Ms Diana Robbins	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	**Position (or reason for attending)**

Ms Katy Cassidy	Confidentiality Advisor
Rekha Keshvara	HRA Approvals Manager (Observer)

1. Introduction, apologies and declarations of interest

Item 5a – 22/CAG/0009 Professor Lorna Fraser declared a potential interest as she knew the Chief Investigator and works in the same institution. Professor Fraser had no involvement in the application and the CAG decided that she could remain in the meeting for this discussion.

2. Support decisions

Secretary of State for Health & Social Care Decisions

No non-research applications were discussed at the **02 December 2021** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **02 December 2021** meeting applications.

3. Annual Reviews

Context

The Clinical Practice Research Datalink (CPRD) has been operating under Regulation 5 support since 2012 for NHS Digital to act as a trusted third party in order to link data from numerous sources. The CPRD is a function of the MHRA. The application sets out the activity to process a broad range of specified datasets by NHS Digital, and to enable de-identified disclosures to research applicants by the CPRD, following review through the Research Data Governance (RDG) process. Due to its national nature, the annual review is considered at full CAG meetings.

CPRD was previously supported under reference ECC 5-05 (a)/2012. In June 2020, the applicants were asked by the CAG to submit an updated application due to changes in the regulatory and legal landscape since 2012, some press interest, the age of the enterprise and the increase in its scale. This is the first annual review submitted since the updated application was supported.

At a high level, support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 has been provided for the following aspects:

- NHS Digital to receive identifiers, undertake linkages and provide the CPRD a de-identified dataset. While CPRD is not receiving identifiers directly, it is important to recognise that for the purpose of transparency, NHS Digital is processing identifiers on behalf of CPRD under this legal support.
- GP practices and specified others (according to the approved 'Master Dataset' list) to transfer confidential patient information to NHS Digital.
- NHS Digital is operating under the direction of the MHRA (via CPRD). The applicant for the purposes of this application is the CPRD who are responsible for the actions of NHS Digital (who in turn are operating under instruction of the CPRD).
- The CPRD do not receive identifiable data from NHS Digital or others under the terms of this support. Any processing by CPRD of confidential patient information must rely upon another legal basis.

Confidentiality Advisory Group Advice

Steps taken to anonymise the information or obtain consent from individuals:

Minimum use of identifiers to perform linkage

The applicants noted that NHS Digital acts as CPRD's Trusted Third Party (TTP), to receive and process a defined and minimum number of personal identifiers, patients NHS number, date of birth, postcode and gender. These identifiers are securely and directly provided to NHS Digital by participating GP system providers and relevant third-party controllers, and used by NHS Digital to link to the required datasets. NHS Digital undertake the linkage so that CPRD do not need to receive any identifiers. The identifiers used are the minimum required to ensure accurate linkage.

Practicality of CPRD gaining consent from participants

Due to the large numbers of patents involved, CPRD could not feasibly contact all GP patients individually to obtain consent.

High-risk scenarios – when to refer studies to CAG

The processes for assessing whether a study protocol presents a potential "high-risk" scenario and whether an application needs to be referred to CAG were set out in the 2020 resubmission.

If an application is identified as potentially high-risk, CPRD will discuss with those applying where the re-identification risk could be reduced. Studies may also be

referred to the Research Data Governance (RDG) review process (formerly, the Independent Scientific Advisory Committee (ISAC) review process). The RDG process was described in the protocol. A Risk Management Plan (RMP) may also be sought from the applicants, as well as consideration of possible data minimisation approaches.

Where these applications are deemed by RDG as scientifically robust and are of important public health value, but may appear to pose raised risks of reidentification, they will be referred to the CPRD Senior Management Team (SMT). The SMT will review the application, RMP and RDG reviewer feedback to determine whether the case should be referred on to CAG as potentially 'high risk'.

As noted above, the ISAC (Independent Scientific Advisory Committee) has changed name to RDG (Research Data Governance) process at CPRD. CAG was notified of the change and, as only the name has changed and all processes are unchanged, CAT accepted this as requiring notification only and not a formal amendment.

The CAG noted that, between the period of February 2021 - January 2022, there have been no 'high risk' cases where mitigations have not been possible and that would have needed referral to CAG under the CPRD s251 exemption. Members asked that the criteria for high-risk studies was submitted to the CAG and queried how recently the criteria had been updated. If the criteria had not been updated since the previous submission, the CAG queried how frequently the criteria would be reviewed and updated.

Project changes

The applicants provided information on a number of updates made to CPRD, based on requests and new potential ways of supporting public health. These are listed below, with the CAG comments.

Database REC Submission

A new REC application has been submitted, to replace 05/MRE04/87 with 21/EM/0265. The application is currently going through the REC review process. The IRAS number for this new REC application is 242149. The REC Favourable Opinion was issued after this Annual Review was submitted and has been included.

Proposed amendments to the CPRD application:

New interim head of CPRD

The head of CPRD (Dr. Janet Valentine) left CPRD in October 2021. Drs. Puja Myles and Tim Williams are jointly acting as Director of CPRD in the interim. The CAG noted that an amendment was required, to notify the CAG of this change.

Expansion of Primary Care data

Vision has been the long-standing GP system provider from whom CPRD has sourced data, under agreement from participating GPs. Since 26 July 2021, CPRD started collecting de-identified primary care records from TPP/SystmOne primary care data, under agreement from participating GPs. CPRD is still working with NHS Digital to finalise the process of identifiers flowing from TPP for data linkage (see section 2.ii).This will not change CPRD's operations, purpose or scope.

CPRD continues to only receive de-identified patient data from participating GPs and their system providers, and patient identifiers continue to flow directly from GP system providers to NHS Digital for the purposes of data linkage, as described above.

The CAG noted that currently support does not cover the flow of identifiers from TPP to NHS Digital for linkage, Members agreed that an amendment would need to be submitted to the CAG prior to any identifiers flowing from TPP to NHS Digital.

Update to Master Dataset List (MDL)

The applicants provided an updated Master Dataset List (MDL), which includes the additional datasets supported in May 2021.

The applicants noted in the annual review form that they were unclear on the new Data Controllers for the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) and NHS Abdominal Aortic Aneurysm Screening Programme data (NAAASP) since the dissolution of Public Health England.

The CAG noted that the new Data Controllers for the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) and NHS Abdominal Aortic Aneurysm Screening Programme data (NAAASP) are NHS Digital and NHS England, respectively. Members agreed that, as the changes made were as the result of the dissolution of Public Health England, the applicants would not be asked to submit an amendment.

Patient and Public Involvement and Engagement (PPIE)

The Primary Care Recruitment Team have attended and presented at two Public Patient Group (PPG) meetings to date (10th December 2021). One meeting covered a network of 8 practices in Liverpool CCG and the other was a practice PPG meeting in Kent and Medway CCG. Another three practice PPG meetings are scheduled to take place prior to April 2022 in Barking London, Sunderland and Bristol. Another PPIE workshop is planned to take place in 2022. The CAG noted this information and raised no queries regarding Patient and Public Involvement and Engagement.

Change to the CPRD poster

In the recent resubmission, the REC had requested that the wording of the poster was revised. The CAG reviewed the current wording and the REC suggested wording. Members agreed that they wanted their original wording to remain but were happy for the REC wording to be added.

The CAG suggested that the below wording was used in paragraph two of the poster.

“CPRD is a Government organisation that provides anonymised patient data for research to improve patient and public health. Identifiable data flows to NHS Digital but you cannot be identified from the information sent to CPRD. Identifiable data is used by NHS Digital to link information from your general practice to information from different sources such as hospital information. However, you cannot be identified from the information that is sent to, or held by, CPRD.”

The CAG asked that an amendment for this change was submitted. The amendment was to be processed by the Confidentiality Advice Team.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in this activity continuing, and therefore advised recommending support to the Health Research Authority, subject to compliance with pre-existing standard conditions, and the specific conditions of support as set out below.

Specific conditions of support

1. Please provide the criteria for high-risk studies and advise when the criteria were last updated. If the criteria had not been updated since the previous submission, advise how frequently the criteria would be reviewed and updated.

2. An amendment to be submitted to request support for the flow of identifiers from TPP to NHS Digital prior to any transfer taking place.

3. Amendments need to be submitted for the below changes. The amendments will be processed by the Confidentiality Advice Team:

    a. Amendment to remove Dr Janet Valentine and name Dr Puja Myles and Dr Tim Williams as joint Directors of CPRD.

    b. To revise the wording of the poster, in line with the wording suggested above.

4. Amendments

a. 20/CAG/0116 - Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS)

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating trusts in England and Wales to the Barts Cancer Care (BCC) Safe Haven Environment. The applicants are seeking to include items related to the Sentinel Lymph Node Biopsy (SLNB).

The SLNB is a diagnostic procedure to assess early stage oral cavity and oropharynx cancers. The procedure is relatively new in the UK, therefore the NICE Head and Neck Cancer Quality Standard recommends that hospitals measure the proportion of people with early stage oral cavity cancer who do not need cervical access as part of surgical management and who have sentinel lymph node biopsy as an alternative to elective neck dissection. Hospitals are also asked to record the surgery-related morbidity and length of stay for people with early-stage oral cavity cancer. The SLNB data will be collected as an extension of the QOMS registry as part of the current data collection cycle (2021-2024). After this period, it will be reviewed based on results and evidence in published literature.

The applicants also seek to collect confidential patient information in retrospective projects. The initial CAG application included a provision to collect data for the oncology and reconstruction component of the registry. This data was to be anonymised data where possible. The applicants have reconsidered whether collecting anonymised data is feasible and are now seeking to include confidential patient information, such as NHS or hospital numbers in each project, and patient dates of birth and postcodes. The applicant advised that amendments would be submitted to the CAG to provide a list of the data items for each project.

In this amendment, the applicants specifically seek to collect retrospective data for orthognathic surgery. This project would be a one-off, with no planned extension and would cover the period 01 January 2017 – 31 December 2019. Patient NHS numbers, date of birth, gender and dates related to their treatment milestones will be collected. Data, including items of confidential patient information, will be retained for 2 years following the end of data collection in order to allow verification for data quality and analysis.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group at the 20 January Full CAG meeting.

The CAG agreed that support for the amendment to include confidential patient information collected for retrospective projects, specifically to collect retrospective data for orthognathic surgery could not be recommended. Members noted that the collection of retrospective data significantly expanded the scope of the project and asked that a new application was submitted. This application should include the current activity undertaken for the Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS) and the collection of SLNB data, as well as the proposed retrospective linkages. The rationale for using patients' hospital number to link to HES, the information needed for linkage to HES and how this would be undertaken needed to be provided. Alternatives to using patient postcodes, such as using Lower Super Output Area, should be explored and, if they can't be used, justification given on why not. Further patient and public involvement needed to be undertaken when preparing the new application. The patient notification materials also needed to be revised and expanded to include the retrospective data linkage.

The CAG agreed to recommend support for the addition of items related to the Sentinel Lymph Node Biopsy, provided that clarification was provided over the data flows involved.

The applicant provided responses to the below queries:

1. **Further details on the revised data flows, including the flow of information for the SNLB, need to be provided.**

The applicant advised that no changes to the data flow were required, as the new items collected for the SLNB are an extension of the current Oncology & Reconstruction dataset. The dataflow for SLNB therefore remains the same as the one submitted in the original CAG application. The CAG noted this information and raised no further queries.

2. **Please clarify whether the SLNB data is obtained from an existing, centralised database or if this data collection will require an additional data flow from each participating trust? If the former, please provide further details on this database.**

The applicants explained that some surgeons may maintain records for their own patients. The applicants aim to establish a centralised data collection for SLNB. An additional data flow will be required from each participating trust. The applicants will apply to each participating trust to update the existing approval to include SLNB. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

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

   Confirmed: The NHS Digital 2020/21 DSPT review for Barts CR-UK Centre was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 December 2021)

5. New Applications

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

Context

Purpose of application

This application from the University of Sheffield set out the purpose of medical research that seeks to assess the feasibility of urinary self-testing for non-visible blood (non-visible haematuria - NVH) as an early detection method for bladder cancer.

Yorkshire has some of the lowest survival rates from bladder cancer in Britain. Improvements in survival could be delivered through earlier diagnosis by screening individuals at high risk of dying from this cancer. The detection of NVH in urine could be a way of detecting bladder cancer early in people without symptoms. The applicants are seeking to understand the best method of identifying and testing before starting a larger early detection trial across Yorkshire.

In this feasibility study, the applicants will send urine self-testing kits to three cohorts. In cohort 1, 2000 urine self-testing kits will be sent to screen-engaged participants of the Yorkshire Lung Screening Trial (YLST). In cohort 2, 3000 urine self-testing kits will be sent to eligible men (65-80 years). Participants in these two cohorts will self-test their urine up to six occasions. Those with NVH detected in the urine will undergo further urine testing (for cancerous cells) and an ultrasound scan at a study clinic. Those with suspected cancer will be referred to their local hospital. In cohort 3, 1000 self-testing kits will be sent to 1000 NHS patients being investigated for potential bladder cancer in the 2 week wait (2WW) pathway.

The applicants require support to identify and contact two of the three cohorts involved in the study:

- Cohort 2 will be identified through a database search of 8-10 selected GP practices located in the Sheffield, Rotherham, Doncaster, and Barnsley CCG areas in South Yorkshire and identified to be in a high-risk bladder cancer mortality region. The applicants also seek to retain confidential patient information from all participants in Cohort 2, whether they respond to the invitation for urine self-testing or not, so that follow-up data can be obtained from NCRAS for the whole cohort.
- Cohort 3 participants will be identified through 2WW referral lists for the investigation of haematuria at participating NHS Trusts. Contact details for this cohort will be shared with King's College London and Testcard Ltd, the mailing company. Processing of confidential patient information may also be undertaken by the local research nursing teams, who may be outside of the direct care team, depending on individual trusts.

Cohort 1 will be identified via the YLST. This cohort is outside the scope of support, as they will give consent to be contacted about research projects before they are sent information about the YORKSUre study.

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	Cohort 1: Men and women aged 55-80 years within the YLST. 2000 patients.

	Cohort 2: Men aged 65-79 years registered with a selected GP in a region with a high BCa mortality risk. 3000 patients. Cohort 3: Men and women aged 65-79 years referred by GPs with visible haematuria (VH) or non-visible haematuria (NVH) to urological departments at participating NHS Trusts. 1000 patients.
Data sources	1. National Cancer Registration and Analysis Service (NCRAS) 2. Patient records at participating GP practices 3. Patient records at participating NHS hospital trusts.
Identifiers required for linkage purposes	1. Name 2. NHS number 3. GP registration 4. Date of birth 5. Address 6. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Address 3. Postcode – unit level

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. The CAG agreed that the application had a medical purpose and was in the public interest.

- **Minimising flows of identifiable information**

The proposed data flows were complex, requiring disclosure of confidential patient information to iPlato and the local research teams, then King's College London, then the mailing company. The CAG asked the applicants to explore alternate ways of conducting the data linkage to reduce the number of disclosures required.

- **Feasibility of consent**

Patients in Cohort 1 will have given consent to be contacted about taking part in research and are outside the scope of support sought.

For Cohorts 2 and 3, the applicants advised that it would not be practicable for the holders of the information, the participating GP practices and NHS trusts, to undertake the consent process due to lack of resources. Also, the applicants are conducting a feasibility study, which may lead to a full study, and need to test that the methods used can be scaled up to the larger scale trial. The applicants also noted concerns that implementing a consent process prior to identification for mailout may negatively impact on the assessment of the primary endpoint, uptake, as only participants who gave consent would be invited to the study.

The CAG agreed that consenting prior to sending the invitation letter was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to identify eligible patients and to send the invitation letters. This cannot be undertaken in any other way.

Recruitment to study

Patients would initially be contacted via text. Members noted that limited information could be provided in a text and receiving a text unexpectedly may be dismissed as spam. The CAG suggested that initial contact was instead made by letter, as more details could be provided.

The CAG expressed concern that the Invitation letter and Information Sheet explained that the aim of the study is to see if urine screening is a good option for picking up possible health problems which may affect the bladder, and that these health problems could include bladder cancer. The patient facing information did not explain that the purpose of the study was assessing the feasibility of urinary self-testing for non-visible haematuria as an early detection method for bladder cancer. The patient information needed to explain that the health check was being performed as part of a study into detecting bladder cancer. The documents also need to explain that the "health registry data" will be obtained from NCRAS and that the NHS routinely collect cancer data.

The CAG noted that the Information Sheet that accompanied test pack is better worded than the primer letter. Members suggested that the primer letter was not used and instead that the testing pack and Information Sheet were sent.

The applicants had stated that implied consent would be relied on for linkage of patient data to NCRAS data. The CAG advised that this was not correct and asked that patients were asked for specific consent for the linkage of their data to NCRAS.

Patients in cohort 2 would receive the primer letter before receiving the testing kit, but it was unclear whether cohort 3 would also receive the primer letter in advance. If the CAG suggestion of not sending the primary letter was not followed, members asked that it was clarified whether patients in cohort 3 would receive the primer letter. If patients in cohort 3 would not receive the primer letter in advance, please provide justification on why not.

The CAG noted that part of the feasibility study was assessing how many patients would return the test kit. Members asked whether there was a target for the minimum number of responders and whether the applicants would continue to contact patients until the minimum was met.

'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.

Before patients in Cohort 2 are identified, fair processing notices will be displayed in the GP practices, on GP practice websites and on the study website. They will be displayed for 4 weeks before the invitations are sent out. The fair processing notice contains

telephone, email and postal contacts. Patients in Cohort 2 may opt out of being contacted, providing the database search hasn't yet been conducted. Any patients dissenting from being contacted will be removed from the data extract. The invitation letter and participant information booklet for Cohort 2 will contain information on the options for opt-out which includes an opt-out via the YORKSUre freephone number. Participants can also email the YORKSUre study team to opt-out. The applicants advised that iPlato have confirmed that the National Data Opt-Out will be applied to the Cohort 2 data.

The applicants advised that there will be no opportunity for patients in Cohorts 1 and 3 to opt-out of being contacted and sent a kit in the initial approach. For Cohort 2, invited participants will have the opportunity to express dissent to data use (for passive follow-up with NCRAS) for the trial and to ensure no reminders are sent to the participant.

The applicants sought to retain information for all patients contacted, including those who did not respond. The CAG advised that, following the Information Commissioner's Office guidance that non-responders are considered to have dissented, it is not possible to include non-responders in the linkage to NCRAS data. The CAG suggested that one reminder letter was sent after the initial approach, and then patients should be treated as non-responders and their confidential patient information deleted.

The patient notification for cohort 2 needed to contain a link to the study website. The patient information also needed to explain that patients information will be deleted if they do not respond.

The CAG requested confirmation that patients in cohort 3 were provided with the same patient notification materials as cohort 2.

The CAG agreed that the National Data Opt-Out needed to be applied for patients in both cohort 2 and 3. The patient records for patients in cohort 3 also need to be checked for evidence of historic dissent to use of their data in research.

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.

Patients and public representatives are involved at multiple points in this study. A group of 9 PPI representatives were approached at the grant application stage for initial review of the study design, objectives, lay summary, and survey questions, and their responses have been incorporated in the study design. PPI members have also reviewed the participant facing documentation and provided feedback.

Three one-to-one interviews were also held with individuals to obtain specific feedback on aspects of how the study is presented to potential participants. These individuals are part of different PPI groups including the King's College London Translational Oncology and Urology Research (TOUR) group, and a bladder cancer support group.

A summary of the study and details about the use of patient identifiable information without consent was developed by the study team and sent to 4 PPI reviewers. PPI reviewers were asked to give their opinion on the use of data without consent for study approach (Cohort 2), the use of a third party (mailout company), the collection of follow-up data particularly for those that do not take part, and the opt-out process. The applicants provided information on the demographics of those involved and an overview of the feedback. Following written feedback, a discussion was then held with 2 of the PPI reviewers to discuss their responses to the questions asked. The CAG raised no queries over the patient and public involvement undertaken.

Exit strategy

The exit strategy was consent. The CAG asked that the exit strategy for non-responders was clarified, including confirmation that no data linkage to NCRAS would be undertaken for patients who did not respond and when the identifiers for non-responders would be deleted from the study database.

The CAG asked for clarification on how long Testcard needed to retain confidential patient information to facilitate sending the invitation letters and when this information would be deleted.

Participating trusts

The CAG asked that the list of participating trusts was provided.

Role of the University of Sheffield

The University of Sheffield are described as data controllers, but are not included in the data flow diagram. The CAG asked that the University's role was explained, including clarification that no confidential patient information would be processed at the University of Sheffield.

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.

Request for further information

1. Non responders need to be treated as having dissented. The invitation and mailing letter could be sent, plus one reminder, but any non-responders could not be included in the linkage to NCRAS and their confidential patient information needed to be deleted.

2. Confirm that the patient records for patients in cohort 3 will be checked for evidence of historic dissent to use of their data in research.

3. Provide clarification on how long Testcard need to retain confidential patient information to facilitate sending the invitation letters and when this information will be deleted.

4. The list of participating trusts needs to be provided to the CAG.

5. Alternate ways of conducting the data linkage to reduce the number of disclosures required needs to be explored and feedback on alternatives or reasons why no alternatives can be used provided.

6. The patient information materials need to be revised as follows;

    a. The primer letter should not be sent. Instead, patients should be sent the Information Sheet and test pack as the initial contact.

    b. If the CAG suggestion of not sending the primary letter is not followed, clarify whether patients in cohort 3 will receive the primer letter. If patients in cohort 3 will not receive the primer letter in advance, provide justification on why not.

    c. It needs to be explained that patients' information will be deleted if they do not respond.

    d. The patient notification for cohort 2 needs to contain a link to the study website.

e. The study documentation needs to explain that the health check was being performed as part of a study into detecting bladder cancer.

f. The documents also need to explain that the "health registry data" will be obtained from NCRAS and that the NHS routinely collect cancer data.

7. Patients need to be asked for specific consent for the linkage of their data to NCRAS.

8. Advise whether there a target for the minimum number of participants and if recruitment will continue until the target is met.

9. The National Data Opt-Out needs to be applied for patients in both cohort 2 and 3.

10. The University of Sheffield's role needs to be explained, including clarification that no confidential patient information will be processed at the University of Sheffield.

Specific conditions of support

The following sets out the specific conditions of support.

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. **Confirmed:**

   The NHS Digital **2020/21** DSPT reviews for Testcard Ltd, King's College London and NCRAS (held by NHS Digital) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 28 January 2022)

b. 22/CAG/0007 – Prisoner Health Care

Context

Purpose of application

This application from NCEPOD set out the purpose of a confidential enquiry to review the clinical healthcare provided to prisoners.

The House of Commons Health and Social Care Committee report, 'Prison Health' which was published in 2018, reported that the Government was failing in its duty of care towards people detained in English prisons. The Select Committee recommended that the National Prison Healthcare Board worked with stakeholders to agree a definition of equivalent care and indicators to measure health inequalities between those in prison and the general population. The application has been commissioned by the Health Foundation, supported by NHS England, to review of the healthcare provided to prisoners who died in prison. The information collected will be used to highlight where care and organisation of care could be improved.

The standard NCEPOD methodology will be followed. A retrospective peer review of clinical notes will be undertaken and those involved in prisoners care will be asked to complete a questionnaire to provide their views on the care they could provide.

The Prisons and Probation Ombudsman (PPO) produce Fatal Incident reports for any prisoner who dies. The Fatal Incident reports will be accessed to identify relevant patients. These reports are in the public domain, therefore this is outside the scope of support. However, as these reviews are undertaken to varying levels of detail dependent on the nature of the death the applicants will undertake more detailed reviews, which will include review of the care provided over the previous 12 months, to assess the healthcare provided as well as the death. Information for identified patients will be linked to prison healthcare and primary care records at SystemOne, and hospital case notes if the prisoner was admitted to hospital. NHS commissioned independent clinical reviews, provided by NHS England/Health Inspectorate Wales, and coroners inquest reports will also be accessed, if available. For the in-depth peer review, extracts of case notes from hospitals and SystmOne will be scanned and sent to NCEPOD via an nhs.net email address. Questionnaires will be sent to the clinician involved in the care of the prisoner and confidential patient information is required to send this questionnaire. The data collected will be aggregated before publication and confidential patient information is only required to link data at the collection phase.

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	All prisoners aged 18 years and over who died between 01 January 2018 and 31 December 2020, of natural causes or other non-natural deaths. Deaths where the cause was suicide or homicide will be excluded.
Data sources	1. Fatal Incident Reports, created by the Prisons and Probation Ombudsman 2. Records of the NHS clinical review associated to the Fatal Incident Report 3. Coroner's inquest reports 4. SystmOne notes for the 12 months leading up to the death – held by Primary Care Support England 5. Patient records at the treating hospital for any acute admissions and outpatient appointments in the 12 months leading up to the death
Identifiers required for linkage purposes	1. Name 2. Sex 3. Age 4. Date of birth 5. NHS number 6. Date of death 7. Prison name 8. Hospital name 9. NHS number 10. Hospital number 11. Prisoner number 12. Date of admission – where applicable 13. Date of discharge – where applicable
Identifiers required for analysis purposes	1. Name 2. Sex 3. Date of birth 4. Prison number 5. Hospital number 6. NHS number 7. Date of death

	8. Prison name 9. Hospital name 10. Date of admission 11. Date of discharge

Confidentiality Advisory Group advice
The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services 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 patients who are the subjects of the study will all be deceased. The CAG agreed that consent was not feasible.

- Use of anonymised/pseudonymised data

The applicants require access to confidential patient information in order to identify relevant patients, to link information from various data sources, and to identify the clinicians providing care so that a questionnaire can be sent. The CAG agreed that the activity could not be carried out in any other way.

Justification of identifiers

The CAG noted that a number of identifiers would be processed. Members noted that patient name, date of birth and NHS number should be sufficient to confirm that the correct patient has been identified and queried whether all the identifiers listed were necessary.

‘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 specific poster and information leaflet has been developed and will be supplied for display in prisons. The applicants noted the need to work with prisons INQUEST/Pact/Prison Reform Trust to determine how to best communicate that the study is taking place, recognising language/learning disabilities/literacy barriers to engagement. The applicants provided the Communications Strategy, poster and information leaflet for review.

Social media will also be used to advertise that the study is taking place. NCEPOD Twitter and Facebook accounts will be used. Links will be added to the NCEPOD website, where the poster and information leaflet will be displayed, as well as information for relatives on how to participate in the surveys/focus groups.

The project will be advertised through prisons and the NCEPOD website and social media pages at the end of January and again in February, once the survey for prisoners/ex-offenders and relatives has been finalised. Core clinical data collection will begin towards the end of March 2022. The project will be advertised throughout the data collection phase.

Patient groups and third sector organisations are involved in the study design and will be asked to help share information about the study. These organisations are listed in the communications plan.

The poster and information leaflet contained email, telephone and postal contact details for the study. Should relatives have questions about the study, they will be directed to the NCEPOD Chief Executive to explain the process in more detail. This will cover the confidential handling of the data, the redaction of all received information and the destruction of data at the end of the study. The situation will be handled sensitively, whilst explaining that Secretary of State support to process the data is in place.

The applicants acknowledged a risk that relatives may ask them to ‘shed new light’ on the death of their relative. It will be explained that all the information collected is either

in the public domain or was available to the coroner at the time of the inquest, and that the applicants are piecing the different parts of the story together from individual deaths to see where themes arise across the whole data set, for the benefit of future prisoners rather than focusing on individual cases. NCEPOD is also not a Public Body so is not subject to the Freedom of Information Act.

The National Data Opt-Out can be applied to the core clinical data for the deceased sample of patients, to see whether they had opted out prior to death before any data not already in the public domain is requested. The NHS numbers will be checked via the MESH system. For any participants in the focus groups, the applicants will not have the NHS numbers to apply the National Data Opt-Out. However, a project specific opt-out will be applied. This has been explained in the amended versions of the posters and information leaflets.

The CAG noted that the poster and leaflet contained different information. Although this was largely due to the format, members agreed that the poster was not explicit over the use of confidential patient information, focusing instead on the opportunity to take part in focus groups. Members asked that the poster was revised to contain further details on the use of confidential patient information.

The patient notification materials for current prisoners had not yet been created. The CAG asked that these were provided for review. The application referenced potential issues over low level of literacy among the prison population, but this was not reflected in the patient notification materials. Members agreed that the patient and public involvement to be undertaken needed to include the creation of patient notification for the prison population.

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 noted the sensitive nature of this topic. They wished to avoid surprise to prison staff or make them feel that they were being investigated. The applicants have undertaken extensive communication work with staff within HMPPS, the Director General of Prisons, the National Clinical Quality Lead for Health and Justice, the Royal College of General Practitioners Secure Environments Group and all acute trusts where prisoners may experience inpatient or outpatient healthcare.

The Prison Reform Trust and NCEPOD lay representatives have also been included on the study advisory group. The applicants have also made formal links with INQUEST and the Prison Advice and Care Trust (Pact) as key stakeholders for

involving prisoner's and their families in surveys/focus groups. NCEPOD has a panel of eight 'permanent' lay representatives involved across our work programmes who sign off the protocols and review the data before publication as well as participating in the study advisory groups.

This phase is nearly complete, and the applicants will shortly undertake some more detailed work with INQUEST/Pact/Prison Reform Trust to engage with prisoners/ex-offenders and families of those who have lost a relative who was a prisoner.

The applicants have delayed engagement with prisoners until this process is complete, although they have ensured that an ex-offender is included on the study advisory group. Engagement work with prisoners is now underway. Through links with HMPPS, the applicants have started notifying the prison community. Reassuringly there has been no negative comments about participation in the study so far.

The applicants have also worked with the Prison Reform Trust, INQUEST and Pact to understand how they may be able to access service user/relative engagement. The applicants advised that a meeting with the Prison Advice and Care Trust (Pact) had been arranged for 13 January 2022. The applicants are also liaising with the Prison Reform Trust (PRT) and INQUEST to determine how to best engage with prisoners/ex-offenders and their relatives.

The CAG noted that the involvement and engagement work with prisoners had not yet taken place. Members asked that this was undertaken, including asking the specific question of the use of confidential patient information without consent and the creation of patient notification materials for the prison population.

Exit strategy

The applicants advised that each item of data will be retained only as long as necessary.

Three months after publication all electronic data are anonymised, and all paper data are securely shredded with a certificate of destruction supplied. The CAG raised no queries regarding 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 Secretary of State for Health and Social Care 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.

Request for further information

1. Please provide justification for using all the identifiers listed in section (j).

2. Feedback from the further patient and public involvement to be undertaken needs to be provide. This needs to cover the following areas:
    a. The creation of patient notification materials for the prison population, including ensuring that the information provided is easily understood by those with an average reading ability.

    b. Specific questions on the use of confidential patient information, as proposed in the application, need to be asked during patient and public involvement.

3. The patient notification materials intended for the prison population need to be provided for review.

4. The poster needs to be revised to include information about the use of confidential patient information.

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **2020/21** DSPT reviews for **NCEPOD, The Health Foundation and Primary Care Support England/The Phoenix Partnership** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 26 January 2022).

c. 22/CAG/0006

Context

Purpose of application

This application from King's College London set out the purpose of medical research that seeks to determine whether accurate and early prediction of outcome after cardiac arrest in a pre-hospital setting is possible.

Out of Hospital Cardiac Arrest (OOHCA) occurs in 60,000 patients per year in the United Kingdom and presents a major public health challenge. The mortality remains very poor with <10% survival to hospital discharge from the community and, as a result, the condition has been highlighted as a priority by NHS England and the British Heart Foundation. The applicants are seeking to conduct a prospective study to identify patients admitted with cardiac arrest who are most likely to survive with good outcome. The main aim is to understand which patients are at highest risk of severe brain damage after OOHCA and to validate a previously developed risk score, the MIRACLE2 risk score.

Patients meeting the eligibility criteria will be identified by paramedics treating on scene. The research paramedic at London Ambulance Service NHS Trust will be made aware that a suitable patient has been identified and will access the pre-hospital medical records at this time. Researchers will take 2ml of venous blood for point of care testing at the time of recovery. Patients will then be followed up at 30 days and 6 months to evaluate their outcome. Hospital data will be collected by the clinical research fellow at King's College Hospital NHS Foundation Trust (KCH). This data will be used to perform statistical analyses to understand how well the MIRACLE2 can predict poor outcome at 30 days. Initial recruitment will be under the emergency research provisions of the Mental Capacity Act. All participants at the time of discharge from ITU to a hospital ward confirmed to meet all inclusion criteria will be approached and invited to participate. Their involvement will proceed on a consented basis. The applicants seek support to collect confidential patient information for patients who die during conveyance by ambulance staff or who die at the continuing care site before consent can be sought.

For patients who die during conveyance, the applicants seek support to allow the London Ambulance Service (LAS) access to confidential patient information without consent for data collection and then de-identification prior to sharing with KCH. For patients who die in hospital, Patients NHS number, conveyance date and site of admission will be provided by LAS to KCH research fellow. The research fellow will then contact the local site Principle Investigator who will collect data with e-CRF on NHS computer. A pseudonymised dataset, identifiable by unique study ID number only, will be transferred to KCH.

The applicants seek to include as many people as possible, which may include those in police custody who have not yet been charged and prisoners. The applicants noted that they did not seek to recruit prisoners specifically but would regard them as NHS patients treated by the London Ambulance Service. Prisoners are expected to make up a small percentage of the sample size.

A recommendation for class 1, 3 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 experience an out of hospital cardiac arrest and sustained return of circulation (sustained pulse after recovery for 20 minutes). The total UK sample size is 500.
Data sources	1. Medical records at the London Ambulance Service
Identifiers required for linkage purposes	1. NHS number
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Gender

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

- **Feasibility of consent**

Consent will be sought from patients where possible. However, due to the high mortality rate of OOHCA, it is likely that most patients will die before consent can be sought. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

The London Ambulance Service need to transfer confidential patient information to the researcher at KCH so that the researcher can contact the treating hospital and ensure that data for the correct patient is identified and collected. This cannot be undertaken in any other way.

The London Ambulance Service also need to access confidential patient information for patients who die during conveyance to hospital in order to collect the dataset, will be anonymised before transfer to KCH. The CAG agreed that the application could not be undertaken in any other way.

'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 have developed a poster, which will be displayed at each site. An email will be provided for patients to use to opt-out. The CAG asked that telephone and postal contacts were also provided, noting that patients may have just left the ICU and may not be able to access email.

The applicants advised that they would not promote the study in prisons, as the prison population were not at high-risk of OOHCA. The CAG agreed with this.

The National Data Opt-out will be applied for patients who, after enrolment, have been found to have opted out through necessary channels. This can only occur at the time of obtaining the NHS number and cross-checking this in the NHS spine. In order to respect a patient's right to be included in novel prospective research with consent, the data opt-out process will only apply to those patients who are deceased prior to obtaining consent or consultee approval.

The Participant Information Sheet explains that patients can stop participating, however the information already held by the researchers will be retained. It was unclear whether this information will contain confidential patient information or anonymised information. If the former, the confidential patient information needs to be removed if the patient requests this.

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 approached 4 patients with out of hospital cardiac arrest who were treated at the lead site. Patients were provided with the patient information sheet and a feedback format with a range of questions and areas for suggestions with white space answers. The demographics of the approached patients in the PPI were 75% white British and 25% British Asian Pakistani. Three quarters were male. This reflects the baseline demographics of this condition in the London conurbation and for those projected to be recruited into study.

The applicants also invited two of the out of hospital cardiac arrest survivors to become formal members of the study committee and they have agreed to do so. Biannual meetings will be held with the PPI group to discuss study progress, amendment(s) and any issues.

The CAG agreed that it was not clear whether the patient and public involvement carried out included specific questions over the use of confidential patient information without consent. Members asked that further feedback was provided, including feedback from the discussion of use of confidential patient information without consent. Further clarity was also required over the number of patients consulted, the demographics involved,

and the responses given. The CAG also suggested that further patient and public involvement was undertaken.

Exit strategy

The exit strategy is anonymisation of the dataset. The CAG raised no concerns about 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.

Request for further information

1. The poster needs to include telephone and postal contacts, alongside email details.

2. Clarify whether the details retained if patients withdraw consent will contain confidential patient information or anonymised information. If the former, the confidential patient information needs to be removed if the patient requests this.

3. Further patient and public involvement needs to be undertaken around the use of confidential patient information without consent. Details need to be provided on the number of patients consulted, the demographics involved, and the responses given.

Specific conditions of support

The following sets out the specific conditions of support.

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.

The NHS Digital **2020/21** DSPT review for **the below organisations** were **confirmed** as ‘Standards Met’ on the NHS Digital DSPT Tracker (26 January 2022):

- London Ambulance Service NHS Trust
- King’s College Hospital NHS Foundation Trust
- Barts Health NHS Trust
- Guy’s and St Thomas’ NHS Foundation Trust
- St George’s University Hospital NHS Foundation Trust
- Royal Free London NHS Foundation Trust
- Homerton University Hospital NHS Foundation Trust
- Chelsea and Westminster Hospital NHS Foundation Trust
- Dartford and Gravesham NHS Trust

The NHS Digital **2020/21** DSPT review is **pending** for the **below organisations:**

- Royal Brompton and Harefield NHS Foundation Trust
- Imperial College Healthcare NHS Trust
- Barking, Havering And Redbridge University Hospitals NHS Trust
- The Queen Elizabeth Hospital, King's Lynn, NHS Foundation Trust
- Central and Northwest London NHS Foundation Trust
- Kingston Hospital NHS Foundation Trust
- Epsom and St Helier University Hospitals NHS Foundation Trust
- Croydon Health Services NHS Trust

d. 22/CAG/0003 - Feasibility RCT of GoodSAM for trauma incidents

Context

Purpose of application

This application from the University of Surrey set out the purpose of medical research to explore the feasibility of conducting a future randomised controlled trial to assess the

clinical and cost effectiveness of using GoodSAM live video streaming to improve targeting of emergency medical resources.

Major trauma (MT) is any injury with the potential to cause death or prolonged disability. MT is a leading cause of serious morbidity and mortality. Advanced emergency medical care provided at the scene of an accident can prevent death and improve patient outcomes. Currently, UK emergency services rely on verbal telephone information from incidents to prioritise dispatch. Previous studies have shown at up to 50% of air ambulance deployments and 25% of land ambulance dispatches are inappropriate, highlighting the limitations of decisions based on audio information only. The applicants seek to explore the use of video to improve triage and dispatch decisions. The benefits of using video in other healthcare settings is growing, e.g. for remote healthcare consultation, but evidence is sparse in relation to use in emergency response. GoodSAM uses callers' smartphone cameras to stream live footage directly to the dispatchers, offering unique opportunities to improve precision in dispatch.

This study is comprised of a feasibility trial, with embedded process evaluation and two sub-studies. In the feasibility trial, each eligible call received will be observed by research paramedics, who will collect data on the incident. They will also record the resource/dispatch decision making, noting whether any dispatch decisions are changed once the live stream is shared for calls on the intervention arm. The study research fellow will be present for some of the intervention arm shifts and may observe incidents in order to examine barriers and facilitators to the use of GoodSAM. Following the incident, the research paramedic or research nurse will approach the casualties or their representative to seek consent for access to their medical data. If consent is given, then patient records will be accessed for up to three months after the incident.

Support is required for the main study to undertake the live streaming without patient consent. Support is also needed for the Research Paramedic to use the CAD number to locate surviving casualties and seek consent or a consultee opinion. For deceased patients, support is needed for data collection from patient records, as consent cannot be sought. The Research Paramedic will undertake observation of shifts at the London Ambulance Service, where live streaming of trauma incidents is used routinely, and will be exposed to confidential patient information when undertaking the observations. A Process Evaluation sub-study will also take place, collecting data on fidelity, acceptability and use of GoodSAM and experiences of its use. Although confidential patient information is not required for this, the research fellow may be exposed to confidential patient information incidentally.

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

Confidential patient information requested

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

Cohort	Patients aged 0 and up who are casualties involved in a category 1 or 2 trauma incident. 834 is the total sample size, approximately 250/300 will be included under support. 999 callers who reported the incident (general public or friends/family of the casualty) – outside the scope of support, unless they are also casualties. NHS staff – outside the scope of support
Data sources	1. Computer Aided Despatch (CAD) system at the South East Coast Ambulance Service NHS Foundation Trust and London Ambulance Service NHS Trust Ambulance Trust；and live collection of data whilst observing eligible calls. 2. Patient records at 12 hospitals trusts: a. Frimley Health NHS Foundation Trust b. Ashford and St Peter's Hospitals NHS Foundation Trust c. Surrey and Sussex Healthcare NHS Trust d. Royal Surrey NHS foundation Trust e. East Kent Hospitals University NHS Foundation Trust f. University hospitals Sussex NHS foundation trust (Brighton, St Richards, Worthing, conquest) g. Maidstone and Tunbridge Wells NHS Trust h. Medway NHS Foundation Trust i. Dartford and Gravesham NHS Trust j. St Georges University Hospitals NHS Foundation Trust k. Kings College Hospital NHS Foundation Trust

	l. University Hospital Southampton NHS Foundation Trust East of England Ambulance Trust – only involved in the sub-study of staff wellbeing, which is outside the scope of support.
Identifiers required for linkage purposes	1. Hospital ID number 2. CAD number 3. Age 4. Sex
Identifiers required for analysis purposes	1. Age 2. Sex

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.

Identifiers to be collected

The CAG noted that the full names of the patients would not be collected. Members queried the reason for not including this identifier, noting that they would be in favour of this being collected if needed.

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**

Consent will be sought from trauma casualties, or a consultee if they are unable to consent, after the incident. However, support is needed to include patients initially as they will have been involved in a trauma incident and may be unconscious, or in a presenting condition which may prohibit them from providing informed consent for participation in the study at the time of the event. Some patients may also die before consent can be sought. The CAG agreed that seeking consent prior to the live-streaming was not feasible.

- **Use of anonymised/pseudonymised data**

The applicants require access to confidential patient information in order to livestream the major trauma incident, which cannot be pseudonymised or anonymised.

The Research Paramedic will undertake observation of shifts at the London Ambulance Service, where live streaming of trauma incidents is used routinely, and will be exposed to confidential patient information when undertaking the observations.

A Process Evaluation sub-study will also take place, collecting data on fidelity, acceptability and use of GoodSAM and experiences of its use. Although confidential patient information is not required for this, the research fellow may be exposed to confidential patient information incidentally. The CAG agreed that the application activity could not be conducted in any other way.

'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 have discussed the issue of patient notification with their PPIE representatives. Due to the broad, population-level remit of the study, meaning that any member of the public in South East England could be included, a patient notification

strategy could not be devised. The applicants noted that they were open to suggestions from the CAG. Patients will be able to object to the inclusion of their data when approached for consent.

The CAG considered whether ways of publicising the study, such as radio advertising, could be used. However, members noted that the activity was fairly complex to explain in a short advert and that the information could be misconstrued, leading to patients being concerned that the live-streams could be recorded or saved. The CAG suggested that some notification was undertaken, via posters on trust ITU's and posts on social media. This information needed to contain reassurance that the National Data Opt-Out will be applied. The text of any notification materials needed to be provided to the CAG for review.

The applicants explained that the National Data Opt-Out could be applied at the point where they will seek consent, however the National Data Opt-Out could not be applied at the time of streaming footage from the incident.

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 proposal was presented at a South East Coast Ambulance Service NHS Foundation Trust (SECAmb) Patient and Public Engagement in Research event to gather views to inform the project team's decisions. Comments from SECAmb's research governance group on the lay summary, the benefits of the study, the potential impact on patients and the importance of the research question were sought during the grant submission process.

The applicants also sought input from the general public by distributing an electronic survey via the Kent Surrey Air Ambulance Service Facebook, Twitter and Linked In pages. Two questions were asked in this survey: one to gain views on the acceptability of live streaming accidents and another gain views on whether they felt live streaming from a 999 call would increase psychological harm over and above witnessing the trauma without streaming (questions pasted below). 547 responses were received. 97.8% answered yes to question 1. 81.3% did not feel that streaming would significantly worsen psychological distress.

A lay representative co-applicant has extensive experience of working with senior groups and team working within boards, and will chair the project advisory group (consisting of all co-applicants and members of the research team, as well as other clinical and methodological advisers), meeting four times over the course of the study,

and will also coordinate a separate PPIE panel with 5 members that will also meet four times over the course of the study to advise the research team.

The patient group supported the use of the basic patient level data without consent, with understanding that full consent will be sought for follow-up data. They also supported the use of the live streaming without consent and the rationale for this given the time-sensitive nature and likely clinical state of participants, and potential benefit to them.

Exit strategy

The exit strategy is that consent will be sought from participants recruited into the trial, or a consultee opinion sought if patients are unable to consent.

For both patients who consent and deceased patients, the dataset will be pseudonymised by removal of the CAD number before the dataset is transferred from SECAmb to the University of Surrey.

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.

Request for further information

1. A patient notification strategy needs to be created and the documents provided to the CAG for review.

2. Clarify why patients name is not collected and whether this is required.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 24 January 2022**

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

Confirmed:

The NHS Digital **2020/21** DSPT reviews for London Ambulance Service NHS Trust, University of Surrey and the South East Coast Ambulance Service NHS Foundation Trust were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 07 February 2022).

e. 22/CAG/0002 - Assembling the data jigsaw: Improving MSK research using linked data

Context

Purpose of application

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

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

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

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

Confidential patient information requested

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

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

Confidentiality Advisory Group advice

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 consent was not practicable due to the size of the cohort, noting that the Salford Primary Care sample size is 250,000. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

The applicants require access to confidential patient information to undertake the data linkages. This cannot be undertaken in any other way.

'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 provide a patient notification. This will be displayed in clinics, GP surgeries and relevant websites, which will include the Jigsaw programme website and GP surgery websites.

A placeholder for email, telephone and postal contacts will be included in the notification. These details have not yet been confirmed with NCA staff. The CAG requested confirmation that contact details for patients to register dissent would be included on all patient notification materials.

The notifications to be displayed in the clinics, GP surgeries and websites will contain contact information for the BI team at NCA. Participants who wish to dissent will be asked to email a member of the BI team at NCA with their name, date of birth and address. The patient records can then be located and removed from the study. A record of the patients hashed NHS number and hospital number will be retained to ensure that the patient record is not included in the future. The CAG requested that the Notification document was reviewed, noting that some statements may not be accurate. They specifically noted the second half of the second paragraph on the first page as requiring revision.

NCA will apply the National Data Opt-Out before extracting 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.

Two patient partners have provided comments on the research plans. Two workshops were also held with approximately 10 participants. A multi-media presentation was given to trigger discussion around key issues, including views around the research and the acceptability of methods to utilise linked data from health care records.

The applicants will hold a workshop with a mixture of people who have a diagnosis of Ankylosing Spondylitis (AS) and additional people without a diagnosis of AS. Those without a diagnosis will include some who have some experience of musculoskeletal symptoms, such as chronic pain, and a number of people from the general population. This is to ensure we have views of a wider group of people whose data may be included within this research.

A report will summarise public views on this component of research to be submitted to the CAG, and will also be reported within programme communications materials, including the programme website.

The workshops have not yet taken place. They are planned to take place in early 2022 and feedback can be provided to the CAG. The CAG agreed that feedback from the patient and public involvement, including discussion of the use of confidential patient information as proposed in the application, needed to be provided before support could be recommended. The CAG also asked that involvement was conducted with people with directly relevant experience.

Exit strategy

The data linkage will be time-limited. Once the linkage is complete, the NCA BI team will hash the NHS number and Hospital Record Number. The research team will be able to access the de-identified data in the 'data lake' at NCA. The applicants advised that the 'data lake' is held at NCA and that confidential patient information will not leave this secure environment. Researchers will 'remote in' to access de-identified data. Only research results (outputs) can be removed, and these will first be checked to ensure that they are not disclosive.

The data linkage is anticipated to take 3-6 months. This is the time taken for the BI team at NCA to prepare, link and de-identify the dataset

The application references that the hashing algorithm will be retained by the NCA BI team for ten years. The applicants have since advised that this is no longer the case. NCA will be asked to destroy the hashing algorithm at the end of the study and will retain only the de-identified dataset.

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.

Request for further information

1. Provide confirmation that contact details for patients to register dissent would be included on all patient notification materials.

2. The Notification document needs to be reviewed for accuracy.

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

Specific conditions of support

The following sets out the specific conditions of support.

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. **Confirmed:**

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

6. Any other business

No other business was raised.

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

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date 04 April 2022
Dr Patrick Coyle		
Dr Murat Soncul		
Signed – Confidentiality Advice Team		Date 04 April 2022
Kathleen Cassidy		