Minutes of the meeting of the Confidentiality Advisory Group

26 May 2022 via Zoom

Present:

Name	Role
Dr Tony Calland, MBE	CAG Chair
Dr Patrick Coyle	CAG Vice-Chair
Ms. Clare Sanderson	CAG Alternate Vice-Chair
Dr Martin Andrew	CAG Member
Dr Sandra Duggan	CAG Member
Mr David Evans	CAG Member
Mr. Anthony Kane	CAG Member
Mr Andrew Melville	CAG Member
Mr Dan Roulstoune	CAG Member
Mr Umar Sabat	CAG Member

Also in attendance:

Name	Position (or reason for attending)

Ms Emma Marshall	Confidentiality Specialist
Mr Paul Mills	Senior Confidentiality Advisor/Service Manager
Mr Michael Pate	Confidentiality Advisor
Ms Caroline Watchurst	Confidentiality Advisor
Mr Matthew Harris	Head of approvals operations, HRA (Observer)
Ms C Ruth Butlin,	Member of Brighton REC (Observer)
Dr Anita Lim	Chief Investigator (item 3a only)
Professor Peter Sasieni	(item 3a only)
Professor Anne Mackie	The Director of Programmes for UK National Screening Committee (DHSC) (item 3a only)
Professor Jennifer Kurinczuk	Chief Investigator (item 3b only)
Nerina Onion	(item 3c only)
Professor Patrick Doherty	(item 3c only)
Professor Gavin Perkins	OHCAO Chief Investigator (items 3d, 4a & 4b only)
Jill Wood	WCTU Quality Assurance (items 3d, 4a & 4b only)
Adam de Paeztron	OHCAO Study Manager (items 3d, 4a & 4b only)

1. Introduction, apologies and declarations of interest

There were no conflicts of interest declared.

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 **28th April 2022** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **28th April 2022** meeting applications.

Minutes:

The minutes of the following meetings have been ratified and published on the website: **22 April Precedent Set Meeting.**

3. Consideration items - requests for National Data Opt-Out exemption

a. 20/CAG/0086 – YouScreen

Scope of NDO deferral request

This is a research application to provide evidence that self-sampling can improve cervical screening coverage in England and can increase detection and treatment of high grade Cervical Intraepithelial Neoplasia.

Regulation 5 support was initially given for three activities of the study. The first was for the use of a third-party mailing company to invite women to the study after identification by NHS Digital. This activity has completed and is therefore outside the scope of this National Data Opt Out (NDO) deferral request.

The second was for NHS Digital to collate and provide effectively anonymised NHAIS data to the study team at King's College London (KCL). It was since confirmed that NHS Digital have an existing legal basis to collate the data and no identifiers are transferred to KCL. The letter of support was updated on 17 February 2022 to confirm this activity was outside the scope of Regulation 5 support, and therefore the NDO does not apply.

The third activity was for the collection of GP data from across London, via Clinical Commissioning Groups (CCGs). Whilst the transfer of this data to KCL is effectively anonymised, Regulation 5 support is in place because staff at CCGs require access to confidential patient information to collate the data, and are not considered to have a pre-existing legal basis to access this.

As such, the scope of the request to defer the NDO was limited to this third activity relating to the collection of GP data at CCGs.

Confidentiality Advisory Group advice

1. Deferral rationale: technical impacts

The CAG noted the substantial time and effort that the applicants have invested in working with EMIS, who provide the GP platform, and NHS Digital to ensure that the NDO can be applied to the GP data of the study cohort. Ultimately this has not been successful, and members are aware that this situation is somewhat outside the control of the applicants.

However, arguments relating to technical difficulties carry less weighting to disapply the NDO for CAG, given that organisations have had since 2018 to ensure solutions are in place prior to apply the NDO. The deadline for organisations to have the technical solutions in place is 31 July 2022, and CAG were keen for EMIS and NHS Digital to find a solution prior to this date so to ensure that the NDO can be applied to this cohort to allow data to flow. Subsequent to this meeting the Confidentiality Advice Team made enquiries on the ability of EMIS to apply the National Data Opt Out. The applicants are advised to contact NHS Digital to gain assurance that the NDO is properly applied by EMIS, or for further investigations.

2. Deferral rationale: ability to accurately report study data

Members were acutely aware that CAG were being asked to consider two competing policy positions. That being the policy position that patients should have the option of opting out of their patient data being used for secondary uses under Regulation 5 support via the NDO, versus the position to enhance screening uptake for cervical cancer. These positions were carefully considered by members.

The applicant rationale relied upon the fact that the data were required in order to provide a full evidence-based report for consideration of implementing self-screening. If the GP data were not complete this would impact and delay this decision. GP data is also necessary to establish whether self-screening reduces health inequalities. Whilst CAG agree with the importance in reducing health inequalities, members felt that insufficient evidence was provided on how not having all GP data would prevent any conclusions being made on this aspect.

CAG noted that there is a body of evidence of the self-sampling benefits. The applicants stated that UK based evidence on the cost-effectiveness of self-screening, as well as ensuring it fits within the current NHS structure, is lacking.

Members were not convinced by the provided rationale that these conclusions could not be made without all GP data.

Ultimately members agreed that the rationale provided was not sufficient to override patient objections for their data to be used for secondary purposes. CAG were very supportive of the project and purposes as a whole which has a high public interest. However, the most appropriate way to ensure data can flow is for EMIS and NHS Digital to ensure a technical solution is found to ensure Youscreen can access the GP data whilst ensuring patients objections are respected.

Patient and Public Involvement

As part of the considerations CAG reviewed the patient and public involvement work undertaken. Members commented that undertaking patient and public involvement with seven women, given the large sample size and different cohorts of women involved, was not sufficient to provide a considered output, though noting that the study team felt that undertaking in-depth patient and public involvement with these women would provide more meaningful data.

Six of the seven women were broadly supportive of the NDO to not be applied. Whilst members considered these views, they were also aware that one woman was strongly against the idea to not apply the NDO. The applicant stated that this woman provided written comments only, and that as such they were unable to interact with her and further understand her reasoning.

Further, the applicants reasoned that some women consented to their samples being used but had separately applied their NDO and were concerned that their GP data will not be used. However, lay members of CAG also commented on the opposite situation where women may have actively not participated by not consenting for sampling and applied their NDO which, given the reasoning above, cannot be ignored.

CAG were appreciative of the patient and public involvement work undertaken to support this request but ultimately it was not sufficient to override the previously described concerns.

Confidentiality Advisory Group advice conclusion

Members carefully considered this request to defer the NDO, with the primary rationale reliant on the technical difficulties and the impact applying the NDO will have in providing a recommendation for self-screening to be introduced for cervical cancer. However, CAG ultimately concluded that the potential impacts stated by the applicants were not sufficient to override a patient's objection, through the NDO, for their data to be used for secondary uses as part of this application.

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. Whilst CAG were sympathetic to the issues faced by the applicants which are outside their control, members agreed that overriding patient rights to disapply the NDO is not the solution. To ensure that the study is able to gain the GP data to report on the effectiveness of self-screening EMIS and NHS Digital, with support of DHSC should endeavour to resolve the technical issues as soon as possible.

The CAG therefore recommended to the Health Research Authority that the National Data Opt-Out deferral request to not be supported.

b. 17/CAG/0150 – National Perinatal Mortality Review Tool (PMRT)

Scope of NDO exemption request

The PMRT application has had Regulation 5 support support since for the implementation of the National Perinatal Mortality Review Tool (PMRT) on behalf of the Department of Health and Social Care (England) and the Welsh and Scottish Governments. The PMRT is wholly integrated with the MBRRACE-UK perinatal mortality surveillance data collection (support under 15/CAG/0119) given both systems are concerned with the same cohort and use the same data to reduce burden.

During the process of using the PMRT to conduct local reviews of care, identifiable and clinical information will be collected and generated. Regulation 5 support is in place specifically to enable this information to be held without parental consent on the MBRRACE-UK servers. Support allows analysis on the improvements made to the perinatal mortality review process following the implementation of the tool.

The submission confirms that the request to defer the NDO is limited to the review of late second trimester miscarriages (20-23 weeks' gestation) and stillbirths (24 weeks' gestation onwards) using the PMRT.

Neonatal deaths and unattended stillbirths are reviewed using the PMRT as part of the statutory obligations of child death review as defined in the Child Death Review Statutory & Operational Guidance of the 'Working Together' Guidance (Oct 2018) of the Children Act 2004. Given the alternative legal basis for neonatal deaths and unattended stillbirths the NDO does not apply to this cohort and outside the scope of this request.

Confidentiality Advisory Group advice

The applicant's primary rationale for requesting the NDO is deferred was that of patient safety. Quality of local reviews in perinatal mortality was poor prior to the implementation of the PMRT, as evidence by a confidential enquiry which demonstrated that the reviews also did not include any parental concerns.

CAG noted the rationale that if the NDO applied it would have direct patient safety implications as the mothers' quality of care would not be able to be reviewed using the PMRT.

Further, given the disproportion and unequal rates NDO application (0%-24%, median 6 % of deaths), applying the NDO would also have wider patient safety implications for both that have applied and those that have not applied the NDO. Where there are high NDO rates there would be no opportunity to learn and ensure that any subsequent service improvement and trust level can take place.

CAG agreed that continued patient safety improvement in maternity services could be impacted if the NDO were applied, and noted the recent Ockenden report into failures in maternity services. Members were also aware that the closely linked application (MMBRACE – 15/CAG/0119) has recently had a request to defer the national data opt out. Given the clear patient safety impacts that the applicants demonstrated members agreed that the NDO should not be applied to activities in this application.

Informing the patient population

In order to ensure that the relevant patient population are informed that the NDO would not be applied the CAG agreed that it would be critical, as a general principle, for clear communication methods around the deferral to be established. CAG noted that a notification and local dissent mechanism is already in place for those patients whose data is processed under Regulation 5 support, and it is expected that this will continue.

During the considerations of MMBRACE CAG requested that patient notification materials were provided, as well as to further explore longer term to add information in maternity notes/app, working with charities and Royal College of Midwives. Given the close relationship between MMBRACE and PMRT the applicant provided with this application website information for PMRT, as well as a poster designed to be used for both MMBRACE and PMRT.

Members were content with the website text for PMRT and no points were raised. With the poster, members felt that the wording regarding not applying the NDO was brief and requested some further detail to recognise why the NDO is not being applied and to detail how the decision was made to not apply the NDO. CAG requested an updated poster within one month of this letter.

Given the closeness of PMRT and MMBRACE, members agreed that the same condition to support to explore to add information in maternity notes/app, working with charities and Royal College of Midwives. CAG requested further information on this by 27 October 2022, to align with the MMBRACE condition of support.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided. Following thorough review of the request rationales, members agreed that rationale on patient safety and public interest were particularly strong, and provided appropriate reasons for advising why the NDO should not be applied to this activity.

Whilst a patient notification strategy was provided, the CAG felt that the applicant could enhance this through use of other avenues such as social media, charities and the Royal College of Midwives. This may help capture some hard to reach groups which do not book into maternity services. As well, it was recognised that updated patient notification materials have yet to be provided and CAG should have oversight of these within one month.

Given that the applicants provided a notification strategy, and the fact that some trusts are starting to apply the NDO which is already causing impacts for MMBRACE CAG therefore recommended, in this specific instance, to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be conditionally approved.

Specific conditions of support

1. Update the poster to provide more specific detail on why the NDO is not applied and how the decision was made.

2. Provide an update to the inclusion of information in maternity notes/app, to use of charities and the Royal College of Midwives, as well as consideration of the use of social media by 27 October 2022.

3. This outcome confirms a change to the original conditions of support. The National Data Opt-Out is not to be applied to patients included in the activities specified in 17/CAG/0150.

4. A local patient objection mechanism must continue to be used

Conflict of Interest

Professor Jennifer Kurinczuk is a CAG Member, however she is currently on a break of service, and did not participate in the discussion, or the development of any recommendation provided by CAG.

c. ECC 3-04 (a)2012 – National Audit of Cardiac Rehabilitation (NACR)

Scope of NDO deferral request

This national audit has had Regulation 5 support since 2012 for clinical teams at Trusts to input data (including identifiers) to a system administered by NHS Digital. NHS Digital remove identifiers from the data and send a monthly pseudonymised dataset to the NACR team at University of York for audit purposes.

Whilst University of York do not receive identifiers this request was to disapply the NDO for the primary data flows that have Regulation 5 support.

Confidentiality Advisory Group advice

This request was considered by members with the provided rationale predominantly relying on patient safety and the complexity of the data. However CAG agreed that the rationale provided was not sufficient to override patients' objections for their data to be shared for secondary purposes under Regulation 5 support.

Scope of request

As part of a provided paper, the applicants reasoned that applying the NDO would mean that clinical teams would be unable to input patent data which would prevent team from tracking patients and be detrimental to their care. CAG considered this rationale veered into direct patient care, something which is outside the scope of Regulation 5 support and for which the NDO would not apply.

Following discussions with the applicants it was clarified that the data is not used for direct patient care and CAG moved onto other patient safety rationale discussions.

1. Deferral rationale: patient safety

Members considered the paper provided by the applicants, where the patient safety reasoning relied on the impact the COVID-19 has had on the way that cardiac rehabilitation is delivered, and the need for NACR to monitor these different modes of delivery.

The applicants further provided rationale at the meeting that cardiac rehabilitation programmes are certified, partly through the use of NACR data. For smaller programmes, the loss of data attributable to the NDO may result in the loss of certification of the programme.

Whilst appreciating these arguments, members could not see a direct patient safety implication if the NDO was applied, noting no substantial examples or evidence were provided either through the provided documents or applicants attendance at the meeting. Indeed, the applicants stated at the meeting that individual patient care will not be impacted by the NDO.

Given the lack of evidence and justification on direct impact on patient safety, members agreed that they could not override patient rights to disapply the NDO.

2. Deferral rationale: complexity of data

Whilst noting the reasoning for why the NDO has technical impacts given the complexity of the data, CAG are mindful that organisations have had since 2018 to resolve these issues. Whilst appreciating COVID may have had an impact, members feel this is sufficient time to resolve any technical issues.

As such, the rationale provided in this area was not considered sufficient to advice disapplying the NDO.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided, and discussion with the applicant during the meeting. Given members felt a sufficient rationale as to why patient safety would be impacted by the NDO was not provided CAG recommended to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request to not be supported.

Separately to this application for NDO deferral, the CAG considered that as the ECC 3-04 (a)/2012 application is now 10 years old, and the Information Governance landscape has changed greatly since the original application was supported, a refreshed application should be made to CAG to supersede ECC 3-04 (a)/2012. This should be provided to CAG at the time of next annual review, instead of the annual review form, and should include a new CAG application form and entire set of supporting documents. This would be prior to 11th June 2023, as this is when the next annual review is due.

d. (reviewed as part of 4a & 4b) 22/CAG/0072 (research) & 22/CAG/0087 (non research) - Out of Hospital Cardiac Arrest Outcomes (OHCA) refresh of ECC 8-04 (c)/2013

Context

Scope of NDO exemption request

The OHCR application has been supported since 2013 as a research database (ECC 8-04 (c)/2013).

This is a request to defer the National Data Opt-Out for ECC 3-04 (a)/2012. Support has been in place for disclosure of confidential patient information from participating NHS ambulance trusts to the University of Warwick for inclusion in the OHCAO database, and the disclosure of confidential patient information to NHS Digital for linkage to outcome data and the return of the linked dataset to the University of Warwick.

As part of an amendment review in late 2021 a new application was requested due to the change in main outcome variable from survival to discharge to 30 day survival, the changes made with the COPI Notice as the legal basis, and the age of the application. In 2022, the applicants submitted a refreshed research application under reference 22/CAG/0072. A non-research application, reference 22/CAG/0087, was also submitted.

Alongside these applications the applicant has requested an exemption from the national data opt out. Both applications, and the request to defer application of the National Data Opt-Out were considered at the 26 May 2022 CAG meeting. A separate letter has been issued, detailing the outcome of the research and non-research application reviews.

Confidentiality Advisory Group advice

1. **Deferral rationale – introduction of bias**

The supporting paper set out the “chain of survival” for OHCA. The chain of survival contains four steps, recognising that a cardiac arrest has occurred and calling an ambulance, bystanders beginning cardiopulmonary resuscitation (CPR), use of a defibrillator and the return of spontaneous circulation.

The supporting paper explained that health inequalities affecting patient outcomes from OHCA had been identified. Incidence of OHCA is higher in deprived communities and in areas with a higher proportion of minority groups. These communities also experience lower rates of bystander CPR and are less likely to have access to a public access defibrillator. The supporting paper also cited evidence of systematic bias in relation to the targeting of national community CPR initiatives, with the communities in most need having reduced access compared to white, affluent communities.

Application of the National Data Opt-Out is not uniformly distributed through the population and certain geographical regions have a disproportionately high opt-out rate. Several areas with higher opt-out rates have a higher proportion of people living in deprived setting. Some ambulance services, such as the London and North West Ambulance Services, have a higher concentration of Clinical Commissioning Groups (CCGs) with higher opt-out rates, which would limit the ability to compare services and to compare any quality improvement initiatives implemented.

Those over 30 years of age also have a higher opt-out rate than young individuals and more women than men register an opt-out. Most cardiac arrests occur in those over 30 years of age. Gender imbalance also affects the response to cardiac arrest, as women are less likely to receive bystander CPR and defibrillation.

The supporting paper also cited several studies which evidence that people from ethnic minorities are more likely to opt-out. CPR knowledge of the provision of bystander CPR is lower in minority groups and low-income communities.

The supporting paper referenced the Blackpool CCG area as an example of a CCG with high opt-out rates. The rate of opt-out was 10.3% in September 2021, double the national average. Data from the OHCAO registry has highlighted Blackpool as a cardiac arrest “hot spot,” characterised by a high incidence of OHCA, low bystander CPR rates and poor access to community defibrillators.

2. Deferral rationale – Patient Safety

Two arguments relating to patient safety were presented in the NDO Deferral Request supporting paper.

The first relates to access to community training and defibrillators. The chances of surviving an OHCA are increased if bystander CPR and defibrillation are undertaken. These two interventions form the basis of the NHS Long Term Plan for improving outcomes from cardiac arrest. The NHS and charities require up to date information on where cardiac arrests occur frequently, and locations where the rates of bystander CPR are low or where access to a public access defibrillator is limited, to enable targeted interventions to the areas of greatest need. If the National Data Opt-Out is applied, then the loss of data related to incidences of OHCA in a particular location may result in a failure to provide lifesaving training and equipment, such as defibrillators, in locations identified as having low rates of bystander CPR and defibrillator availability and/or use.

The second relates to the ability of the NHS to monitor variations in outcomes and implement quality improvement initiatives. Information from the OHCA Outcomes (OHCAO) Registry forms the basis of the NHS England National Ambulance Quality Indicators for cardiac arrest. This information is used to manage and support performance of ambulance services to this key patient safety metric. Reports for individual ambulance services are also generated to enable services to benchmark their performance against that of other services, and to drive quality improvement programmes. The loss of data resulting from application of the National Data Opt-Out may undermine the reliability of these comparisons and, potentially, would undermine the quality assurance processes developed to improve patient safety.

3. Deferral rationale – Public interest

Currently, around 10% of patients who experience an OHCA survive to discharge from hospital. The OHCAO Registry was set up to collect data for use to improve outcomes of OHCA. The NHS Long Term Plan set out how the OHCAO Registry will be used to track survival rates, target high-risk neighbourhoods to inform community interventions and to determine where public access defibrillators should be placed, and to enable ambulance services to benchmark their performance and drive quality improvement

initiatives. Data from the 11 England Ambulance Services are collected and sent to NHS England on a month basis for use in reporting of the National Ambulance Quality Indicators.

The OHCAO Registry are also working with NHS Digital to make the registry data available within NHS Digital's Trusted Research Environment. This will facilitate linkage to other databases, such as the Intensive Care National Audit Research Centre, GP records, Hospital Episode Statistics. This data would then be used to expand understanding of health inequalities, the development of prognostic tools, and monitoring and assessment of changes in outcomes.

Confidentiality Advisory Group Conclusion

Following thorough review of the request rationales, members agreed that rationale on patient safety and public interest had not been sufficiently set out to enable deferral of the National Data Opt-Out for both the research and non-research applications.

The CAG agreed that the argument for deferring application of the National Data Opt-Out to the non-research application was stronger than that for the research application, due to the activities described and that data was provided directly back to ambulance services for use in improving care.

The CAG agreed that it was difficult to differentiate between the research and non-research purposes of the database. The research purposes of the Registry were aimed at improving patient outcomes and were very closely linked to quality improvement. The applicants worked closely with NIHR and NHS England, as well as charitable partners, to develop the direction of research. Research also had a policy focus, making it difficult to separate research and quality improvement work. The database is currently a single database. The applicants were considering creating separate databases or including a filter which restricts access to data for patients who had opted-out from use of their data solely in research purposes. However, a clear process for doing this had not yet been created.

Members agreed that, due to the difficulty in separating the research and non-research purposes of the OHCAO Registry, deferral of the National Data Opt-Out would either need to be granted for both research and non-research applications or not granted for either.

The CAG requested details on what the OHCAO Registry had achieved so far. The OHCAO Registry had been used to identify cardiac arrest "hot spots," defined as areas with a high incidence of OHCA and where community response is sub-optimal. The Registry team had worked with NHS England to address key issues. NHS England had commissioned St John Ambulance to use data to target ambassadors

within communities, with the aim of improving bystander CPR. This project had started 6 months ago and will run for three years.

Public access to defibrillators was also analysed. Access to defibrillators was not evenly distributed across communities. The British Heart Foundation and other charities were working to identify places with poor provision and provide defibrillators to these communities.

Blackpool had been highlighted as on outlier, but no other examples had been given. Members expressed uncertainly on whether Blackpool was a complete outlier or if other areas had been identified as similar “hot spots.” The CAG agreed that a strong enough argument had not been made as to why the public would be at a greater risk if the National Data Opt-Out was applied.

Regarding Blackpool specifically, members noted that Blackpool covered a large area and contained areas that were economically deprived and some very wealthy areas. It would be possible for defibrillation availability to be compared against deprivation scores to identify where interventions were needed. This comparison could be made without use of patient data and would, therefore, not be affected by application of the National Data Opt-Out.

Members had considered different ways that the deferral request could have been supported, but these options were not available due to the infrastructure of this specific project. The CAG considered the arguments presented around patient safety and the potential impact of bias, and agreed that the arguments provided were not sufficient to recommend deferral of the National Data Opt-Out.

The CAG agreed that sufficient evidence had not been provided on how application of the National Data Opt-Out would impact on the OHCAO Registry meetings its’ aims. The supporting paper had detailed what they hoped to achieve, however the Registry had been running since 2013 and no evidence of how the project had improved care and patient outcomes had been provided.

4. New applications

a. 22/CAG/0072 - Out of Hospital Cardiac Arrest Outcomes (OHCA) refresh of ECC 8-04 (c)/2013 (research)

Context

Purpose of application

This application from the University of Warwick set out the purpose of medical research, under reference 22/CAG/0072, that seeks to collect and summarise data to be used to improve outcomes of Out of Hospital Cardiac Arrests.

The Out of Hospital Cardiac Arrest Outcomes Project was started in 2013 to establish a database of patients who had a OHCA and where resuscitation was attempted, under CAG reference ECC 8-04 (c)/2013. In November 2021, the applicants submitted an amendment seeking support to include an additional data linkage from NHS Digital, to collect long-term outcome data from NHS Digital, and to increase the frequency of data collection from ambulance services from annual to continuous. The applicants noted that, from May 2021, ambulance services had recorded a new outcome variable, 30-day survival, under the general COPI notice, issued under Regulation 3(4) of the COPI Regulations. The applicants sought to continue receiving this data after the COPI Notice expired. 30-day survival would replace survival to discharge as the main outcome variable. A new application was requested, due to the change in main outcome variable from survival to discharge to 30-day survival, the changes made with the COPI Notice as the legal basis, and the age of the application. As part of CAT review, it was identified that OCHAO also has substantial use for non-research purposes, something that was not originally supported. As such, CAT requested that a non-research application was submitted to provide a legal basis for non-research use. A non-research application, under reference 22/CAG/0087, also from the University of Warwick, was submitted, setting out the collection and use of confidential patient information about people who experienced Out of Hospital Cardiac Arrests to be used to produce summary data for quality improvement work with ambulance services, charities and NHS England.

An estimated 60,000 people have an out of hospital cardiac arrest (OHCA) each year in the UK. Resuscitation is not attempted in around 60% of cases and attempted resuscitation by ambulance services occurs in less than 50% of cases. Where resuscitation is attempted, there is significant variability between ambulance services in rates of the return of spontaneous circulation (ROSC) at hospital handover and survival to hospital discharge. The average survival rate is 7% and if this could be increased to the best reported survival rate of 12%, then it is estimated that an additional 1000 lives could be saved each year. Improving survival to levels seen in the best performing health systems, e.g. 21% as is seen in Seattle, US, could save an estimated 4800 lives annually.

The audit teams at participating ambulance services will collect data from patient report forms, ambulance 999 call records, ambulance clinical records and ambulance vehicle tracking systems. The ambulance services will also collect patient outcome data from other NHS providers or systems, such as the Summary Care Record (SCR) at NHS Digital, or directly from NSH Trusts. The OHCAO project has an additional agreement in place with NHS Digital to collect additional variables relating to long-term survival and cause of death. This includes date of death, place of death and cause of death.

The research database is used as a data source for a variety of research projects. External collaborators wishing to access OHCAO data must complete and send in a data sharing request application form outlining their research project and the OHCAO data variables they require. Following an initial informal review by the OHCAO project team the application is sent to the OHCAO Academic Committee for a formal peer review. Data released to external researchers will be anonymised (unless they have their own 's251' support).

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

Confidential patient information requested

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

Cohort	Patients who experienced an OHCA, who were attended by or on behalf of an NHS Ambulance Service and where resuscitation was attempted. Patients who experienced an OHCA during inter-hospital transfer or on acute NHS hospital trust premises, or where there is clear evidence of death defined by the Joint Royal College Ambulance Liaison Committee (JRCALC) Recognition of Life Extinct (ROLE) criteria, will be excluded. The OHCAO registry receives data for approximately 30,000 cases each year. To date the registry holds 255,877 cases. Total cases by the end of the current funding period (2018 to 2023) will be approx. 300,000.

Data sources	1. Participating NHS ambulance services will provide data obtained from patient report forms, ambulance 999 call records, ambulance clinical records and ambulance vehicle tracking systems, and patient outcome data obtained from the Summary Care Record (SCR) at NHS Digital or through direct contact with acute NHS Trusts (which is part of their usual clinical process). 2. NHS Digital a. demographics data, b. Civil Registration Mortality data (ONS) As part of additional queries, linkage with ICNARC mentioned, and linkage to antecedants to OHCA held by NHS D mentioned, but these studies are not yet in place, and we should expect an amendment about each.
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Date of death 5. Postcode – unit level
Identifiers required to be retained in the OHCA database	1. Name 2. Date of birth 3. Date of death 4. Postcode – unit level 5. Gender
Additional information	Two patient identifiers (date of birth and date of death) will be held in the same table as the clinical data. A secondary table will hold the remaining identifiers (surname, forename, NHS number and home postcode).

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 clear public interest and a medical purpose.

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 main reason for not seeking consent is that most patients will die before consent can be sought. Approximately 8-9% of patients survive to be discharged home from hospital. Resuscitation is terminated at the scene of the cardiac arrest in approximately 55% of cases. The remaining 45% are transferred to hospital of which approximately two thirds have resuscitation efforts terminated in the emergency department.

The applicants advised that they have considered whether a consultee opinion could be sought, in line with the Mental Capacity Act. Approaching consultees was not feasible as ambulance services do not routinely collect next of kin details and there is no legal basis other than approval by CAG to release confidential patient information after someone's death.

- **Use of anonymised/pseudonymised data**

The University of Warwick require confidential patient information in order to link the datasets from participating ambulance services. The University also need to disclose confidential patient information to NHS Digital to receive outcome data. The CAG agreed that the project 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 created a plan of action to inform patients and raise awareness within the project population. Patient representatives on the Project Steering Committee will be asked to disseminate information about the project to established patient and carer networks, such as the West Yorkshire Cardiovascular Network Cardiac Patient and Public Involvement CPPI Group and Kenilworth Heart Safe. Details about the project are also made available on the websites for the British Heart Foundation and Resuscitation Council UK, and on the Warwick Clinical Trials Unit Current Trials website. Updates about the project are also given on a regular basis to the Resuscitation Council UK Community and Ambulance and Executive committees, which have patient and public representation. Results of the project are also published in open access medical journals.

The website information will be supplemented at least annually with a press release to media outlets drawing attention to recent key findings from the registry and highlighting key components of our data privacy statement and where further information can be obtained. The applicants have considered a media strategy but have decided against it, as the costs are prohibitive for a charity funded dataset, and additionally applicants found this did not tend to reach the target audience. This decision is supported by patient and public involvement.

The website information text had not been provided at the time of the CAG review. The CAG noted that minimal information was currently available online and agreed that further efforts needed to be made to publicise the study. The website information needed to explain the activity taking place and a link to the Privacy Notice.

The Privacy Notice needed to be written using lay appropriate language. The explanation of the CAG and its role also needed to be revised as follows, “The Confidentiality Advisory Group have recommended that support under Regulation 5 of

the Health Service (control of patient information) Regulations 2002 ('section 251 support') is given for the processing of confidential patient information."

The applicants had requested that application of the National Data Opt-Out was deferred for both the research and non-research applications. A separate letter was provided by the CAG, setting out the outcome of that request, which was that the National Data Opt-Out needed to be applied for both research and non-research applications.

Patient and Public Involvement and Engagement

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

A Steering Committee had been set up to oversee the project. Two patient representatives were included. Patient representatives are required to offer patient views into the strategic direction of the project and provide input as necessary at each stage. The patient representatives present comments from other patients and carers groups when required.

The applicants have primarily consulted with the patient representatives on the Steering Committee. The Cardiac Arrest UK survivors and relatives support group have also been consulted and have provided a letter of support, relating to the applicants request to defer application of the National Data Opt-Out.

The CAG was satisfied by the patient and public involvement activity carried out.

Exit strategy

's251' support is required in an ongoing fashion for continuous new data collection from ambulance services.

The applicants seek to retain confidential patient information for all patients who fulfil the inclusion criteria for the study. For those where a link is successful, applicants will delete first name and surname, retaining date of birth, date of death, postcode and NHS Number for analysis and future linkage purposes. For those where a link is unsuccessful, we will delete first name, surname and NHS Number, retaining date of birth, date of death, and postcode and for analysis

The exit strategy for the retention of confidential patient information is one or more of the following three scenarios, either that funding for the registry is discontinued, the registry is no longer needed and replaced by data flows directly to NHS England and/or NHS Digital, or after 11 years have passed.

The CAG agreed that it was unclear how long confidential patient information was retained for and why retention was necessary. The CAG queried the necessity of retaining confidential patient information long term and whether an alternative, such as NHS Digital retaining confidential patient information and/or a data linkage key, so that the applicants held anonymised data only, could be used.

The applicants had considered creating a separate, anonymised database, which would be made available to third party researchers. The CAG was supportive of this approach and asked for further information on how this could be done and an anticipated time frame for the creation of an anonymised dataset.

Applications from other researchers to access the database

The CAG agreed that details on how requests by other researchers to access the data would be handled needed to be provided. This needed to include information on the application process and how it would be determined whether a project was research or non-research.

NHS Digital Trusted research Environment

The applicants supporting paper for their request for deferral of the National Data Opt-Out noted that the OHCAO Registry are working with NHS Digital to make the registry data available within NHS Digital's Trusted Research Environment. The CAG asked to the kept up to date with the development and this and that the applicant submit amendments, as needed

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. This application supersedes the support in place under ECC 8-04 (c)/2013.

2. Further efforts need to be made to publicise the study;

    a. The website information needs to be provided for review. The information needs to explain the research and non-research activities taking place and include a link to the Privacy Notice.

    b. The Privacy Notice needs to be written using lay appropriate language. The explanation of the CAG and its role also needs to be revised as follows, “The Confidentiality Advisory Group have recommended that support under Regulation 5 of the Health Service (control of patient information) Regulations 2002 (‘section 251 support’) is given for the processing of confidential patient information.”

3. Provide further details on why confidential patient information needs to be retained long term and whether an alternative, such as NHS Digital retaining confidential patient information and/or a data linkage key, so that the applicants hold anonymised data only, could be used.

4. Provide further information on how an anonymised dataset could be done and an anticipated time frame for the creation of this.

5. Details on how requests by other researchers to access the data will be handled needs to be provided. This needs to include information on the application process and how it would be determined whether a project was research or non-research.

6. Confirm that the CAG will be kept updated on the development of work with NHS Digital to make the OHCAO registry data available within NHS Digital’s Trusted Research Environment and that amendments will be submitted, as needed.

7. Favourable opinion from a Research Ethics Committee. **Confirmed: 13/SC/0361**

8. 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 **University of Warwick Clinical Trials Unit and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 26 May 2022).

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

b. 22/CAG/0087 - Out of Hospital Cardiac Arrest Outcomes (OHCA) refresh of ECC 8-04 (c)/2013 (non research)

Context

Purpose of application

This application from the University of Warwick set out the purpose of a non-research application, aiming to collect and summarise data about people who experienced Out of Hospital Cardiac Arrests to be used to produce summary data for quality improvement work with ambulance services, charities and NHS England. A separate research application has also been submitted, under reference 22/CAG/0072.

The OCHAO application has been supported since 2013 as a research database, under reference ECC 8-04 (c)/2013). As part of CAT review it was identified that OCHAO also has substantial use for non-research purposes, something that was not originally supported. As such, CAT requested this application to form a legal basis for non-research use. In November 2021, the applicants submitted an amendment seeking support to include an additional data linkage from NHS Digital, to collect long-term outcome data from NHS Digital, and to increase the frequency of data collection from

ambulance services from annual to continuous. The applicants noted that, from May 2021, ambulance services had recorded a new outcome variable, 30-day survival, under the general COPI notice, issued under Regulation 3(4) of the COPI Regulations. The applicants sought to continue receiving this data after the COPI Notice expired. 30-day survival would replace survival to discharge as the main outcome variable. A new application was requested, due to the change in main outcome variable from survival to discharge to 30-day survival, the changes made with the COPI Notice as the legal basis, and the age of the application. As part of CAT review, it was identified that OCHAO also has substantial use for non-research purposes, something that was not originally supported. As such, CAT requested this application to form a legal basis for non-research use.

An estimated 60,000 people have an out of hospital cardiac arrest (OHCA) each year in the UK. Resuscitation is not attempted in around 60% of cases and attempted resuscitation by ambulance services occurs in less than 50% of cases. Where resuscitation is attempted, there is significant variability between ambulance services in rates of the return of spontaneous circulation (ROSC) at hospital handover and survival to hospital discharge. The average survival rate is 7% and if this could be increased to the best reported survival rate of 12%, then it is estimated that an additional 1000 lives could be saved each year. Improving survival to levels seen in the best performing health systems, e.g. 21% as is seen in Seattle, US, could save an estimated 4800 lives annually.

The audit teams at participating ambulance services will collect data from patient report forms, ambulance 999 call records, ambulance clinical records and ambulance vehicle tracking systems. The ambulance services will also collect patient outcome data from other NHS providers or systems, such as the Summary Care Record (SCR) at NHS Digital, or directly from NSH Trusts. The OHCAO project has an additional agreement in place with NHS Digital to collect additional variables relating to long-term survival and cause of death. This includes date of death, place of death and cause of death.

The research database is used as a data source for a variety of research projects. External collaborators wishing to access OHCAO data must complete and send in a data sharing request application form outlining their research project and the OHCAO data variables they require. Following an initial informal review by the OHCAO project team the application is sent to the OHCAO Academic Committee for a formal peer review. Data released to external researchers will be anonymised (unless they have their own ‘s251’ support).

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

Confidential patient information requested

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

Cohort	Patients who experienced an OHCA, who were attended by or on behalf of an NHS Ambulance Service and where resuscitation was attempted. Patients who experienced an OHCA during inter-hospital transfer or on acute NHS hospital trust premises, or where there is clear evidence of death defined by the Joint Royal College Ambulance Liaison Committee (JRCALC) Recognition of Life Extinct (ROLE) criteria, will be excluded. The OHCAO registry receives data for approximately 30,000 cases each year. To date the registry holds 255,877 cases. Total cases by the end of the current funding period (2018 to 2023) will be approx. 300,000.
Data sources	3. Participating NHS ambulance services will provide data obtained from patient report forms, ambulance 999 call records, ambulance clinical records and ambulance vehicle tracking systems, and patient outcome data obtained from the Summary Care Record (SCR) at NHS Digital or through direct contact

	with acute NHS Trusts (which is part of their usual clinical process). 4. NHS Digital a. demographics data, b. Civil Registration Mortality data (ONS) As part of additional queries, linkage with ICNARC mentioned, and linkage to antecedants to OHCA held by NHS D mentioned, but these studies are not yet in place, and we should expect an amendment about each.
Identifiers required for linkage purposes	6. Name 7. NHS number 8. Date of birth 9. Date of death 10. Postcode – unit level
Identifiers required to be retained in the OHCA database	6. Name 7. Date of birth 8. Date of death 9. Postcode – unit level 10. Gender
Additional information	Two patient identifiers (date of birth and date of death) will be held in the same table as the clinical data. A secondary table will hold the remaining identifiers (surname, forename, NHS number and home postcode).

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 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 clear public interest and a medical purpose.

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 main reason for not seeking consent is that most patients will die before consent can be sought. Approximately 8-9% of patients survive to be discharged home from hospital. Resuscitation is terminated at the scene of the cardiac arrest in approximately 55% of cases. The remaining 45% are transferred to hospital of which approximately two thirds have resuscitation efforts terminated in the emergency department.

The applicants advised that they have considered whether a consultee opinion could be sought, in line with the Mental Capacity Act. Approaching consultees was not feasible as ambulance services do not routinely collect next of kin details and there is no legal basis other than approval by CAG to release confidential patient information after someone's death.

- **Use of anonymised/pseudonymised data**

The University of Warwick require confidential patient information in order to link the datasets from participating ambulance services. The University also need to disclose confidential patient information to NHS Digital to receive outcome data. The CAG agreed that the project 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 created a plan of action to inform patients and raise awareness within the project population. Patient representatives on the Project Steering Committee will be asked to disseminate information about the project to established patient and carer networks, such as the West Yorkshire Cardiovascular Network Cardiac Patient and Public Involvement CPPI Group and Kenilworth Heart Safe. Details about the project are also made available on the websites for the British Heart Foundation and Resuscitation Council UK, and on the Warwick Clinical Trials Unit Current Trials website. Updates about the project are also given on a regular basis to the Resuscitation Council UK Community and Ambulance and Executive committees, which have patient and public representation. Results of the project are also published in open access medical journals.

The website information will be supplemented at least annually with a press release to media outlets drawing attention to recent key findings from the registry and highlighting key components of our data privacy statement and where further information can be obtained. The applicants have considered a media strategy but have decided against it, as the costs are prohibitive for a charity funded dataset, and additionally applicants found this did not tend to reach the target audience. This decision is supported by patient and public involvement.

The website information text had not been provided at the time of the CAG review. The CAG noted that minimal information was currently available online and agreed that further efforts needed to be made to publicise the study. The website information needed to explain the activity taking place and a link to the Privacy Notice.

The Privacy Notice needed to be written using lay appropriate language. The explanation of the CAG and its role also needed to be revised as follows, “The Confidentiality Advisory Group have recommended that support under Regulation 5 of the Health Service (control of patient information) Regulations 2002 (‘section 251 support’) is given for the processing of confidential patient information.”

The applicants had requested that application of the National Data Opt-Out was deferred for both the research and non-research applications. A separate letter was

provided by the CAG, setting out the outcome of that request, which was that the National Data Opt-Out needed to be applied for both research and non-research applications.

Patient and Public Involvement and Engagement

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

A Steering Committee had been set up to oversee the project. Two patient representatives were included. Patient representatives are required to offer patient views into the strategic direction of the project and provide input as necessary at each stage. The patient representatives present comments from other patients and carers groups when required.

The applicants have primarily consulted with the patient representatives on the Steering Committee. The Cardiac Arrest UK survivors and relatives support group have also been consulted and have provided a letter of support, relating to the applicants request to defer application of the National Data Opt-Out.

The CAG was satisfied by the patient and public involvement activity carried out.

Exit strategy

's251' support is required in an ongoing fashion for continuous new data collection from ambulance services.

The applicants seek to retain confidential patient information for all patients who fulfil the inclusion criteria for the study. For those where a link is successful, applicants will delete first name and surname, retaining date of birth, date of death, postcode and NHS Number for analysis and future linkage purposes. For those where a link is unsuccessful, we will delete first name, surname and NHS Number, retaining date of birth, date of death, and postcode and for analysis

The exit strategy for the retention of confidential patient information is one or more of the following three scenarios, either that funding for the registry is discontinued, the registry is no longer needed and replaced by data flows directly to NHS England and/or NHS Digital, or after 11 years have passed.

The CAG agreed that it was unclear how long confidential patient information was retained for and why retention was necessary. The CAG queried the necessity of retaining confidential patient information long term and whether an alternative, such as NHS Digital retaining confidential patient information and/or a data linkage key, so that the applicants held anonymised data only, could be used.

The applicants had considered creating a separate, anonymised database, which would be made available to third party researchers. The CAG was supportive of this approach and asked for further information on how this could be done and an anticipated time frame for the creation of an anonymised dataset.

Applications from other researchers to access the database

The CAG agreed that details on how requests by other researchers to access the data would be handled needed to be provided. This needed to include information on the application process and how it would be determined whether a project was research or non-research.

NHS Digital Trusted research Environment

The applicants supporting paper for their request for deferral of the National Data Opt-Out noted that the OHCAO Registry are working with NHS Digital to make the registry data available within NHS Digital's Trusted Research Environment. The CAG asked to the kept up to date with the development and this and that the applicant submit amendments, as needed

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Further efforts need to be made to publicise the study;

    a. The website information needs to be provided for review. The information needs to explain the research and non-research activities taking place and include a link to the Privacy Notice.

    b. The Privacy Notice needs to be written using lay appropriate language. The explanation of the CAG and its role also needs to be revised as follows, “The Confidentiality Advisory Group have recommended that support under Regulation 5 of the Health Service (control of patient information) Regulations 2002 (‘section 251 support’) is given for the processing of confidential patient information.”

2. Provide further details on why confidential patient information needs to be retained long term and whether an alternative, such as NHS Digital retaining confidential patient information and/or a data linkage key, so that the applicants hold anonymised data only, could be used.

3. Provide further information on how an anonymised dataset could be done and an anticipated time frame for the creation of this.

4. Details on how requests by other researchers to access the data will be handled needs to be provided. This needs to include information on the application process and how it would be determined whether a project was research or non-research.

5. Confirm that the CAG will be kept updated on the development of work with NHS Digital to make the OHCAO registry data available within NHS Digital’s Trusted Research Environment and that amendments will be submitted, as needed.

6. 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 **University of Warwick Clinical Trials Unit and NHS Digital** were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 26 May 2022).

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

c. 22/CAG/0078 - EXTEND study – Needs Assessed Care for Early Psychosis

Context

Purpose of application

This application from the University of Oxford (with the controller for the activity confirmed to be the same) set out the purpose of medical research which aims to develop a more tailored approach to participants undergoing Early Intervention in Psychosis (EIP) treatment, based on the needs of each individual and understand the health, social, and cost benefits of this approach.

The study will use data from the annual National Clinical Audit of Psychosis that measures aspects of care that individuals receive from every EIP service across England. The study will link audit data to routinely collected NHS hospital records. By identifying differences between people who receive longer or shorter EIP treatment, the research team can see whether differences in length of EIP care lead to different outcomes. They will also find out how differences in duration of EIP influence the short- and long-term cost-effectiveness of the service.

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	Those aged between 14 yrs and 65 yrs who took part in the 2019, 2020 and 2021 National Clinical Audit of Psychosis – approx. 30,000 records, though the same person may have taken part in all 3 audits, thus the number of people taking part will be less than 30,000.
Data sources	5. Royal College of Psychiatrists National Clinical Audit of Psychosis (NCAP) 2. NHS Digital Hospital Episode Statistics (HES) Mental Health Services Dataset (MHSDS)
Identifiers required for linkage purposes	11. NHS number 12. Gender 13. Age 14. Partial postcode
Identifiers required for analysis purposes	11. Date of Death 12. District-level postcode will be used to produce local area-based deprivation measures (IMD), but the postcode will then be destroyed.

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The CAG noted that date of death was being collected for analysis purposes. It was not clear whether the date of death could be redacted to month and year of death, in order to conduct the data analysis. The CAG wished to know if date of death could be redacted to month and year of death in order to conduct the data analysis.

If full date of death was required for the analysis, the applicant needs to be clear as to how long for (providing a date), so that the length of 's251' support can be ascertained. If date of death could be redacted into a less identifiable format, the applicant needs to be clear about how long data linkage would take and therefore when 's251' support can end (providing a date).

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 applicant stated that there is no reasonable alternative to matching personal identifiable data on NCAP subjects without consent. The planned study requires data on a large, representative population of EIP service users drawn from the whole population of EIP teams. Obtaining consent from all of these individuals is not logistically feasible. In a study where explicit consent was sought, those not consenting would be unlikely to be missing at random, creating a bias in the results and therefore undermining the validity of the study.

The CAG accepted that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Without being provided with identifiers by the Royal College of Psychiatrists, then NHS Digital could not link the data to their own datasets and provide the appropriate full pseudonymised dataset for analysis. The applicants had provided confirmation from NHS Digital of the identifiers needed for linkage and that NHS Digital were willing to carry this out. The CAG accepted the explanation.

'Patient Notification' and mechanism for managing dissent

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

A privacy notice, including how to opt out of the study has been developed in collaboration with the Patient and Public Involvement co-investigators and will be publicised prior to the proposed linkage including through notices on the Royal College of Psychiatrists website, and social media. The linkage of data will be one-off and retrospective. The opportunity to withdraw consent will take place before the linkage has been undertaken, as no identifiable data will remain in the linked dataset available to researchers making it impossible to remove individual records. The privacy notice is enclosed with the application.

There are opt-out procedures in place for the national audit. Participants can opt out via their NHS Trust or the NCAP team. The NCAP team comply with the National Data Opt-Out.

The two methods available for opt-outs are:

1. Contact the Royal College of Psychiatrists, who will remove the individual from the linkage if requested. This method can also be used to opt out of the NCAP entirely and is advertised as such in public notices regarding the NCAP.
2. Request an opt-out from any NHS Digital data sharing. This will ensure that no records held by NHS Digital are linked to the data provided from the NCAP. This method is available to the general public and will opt out the individual from any data linking conducted by NHS Digital.

As part of the NCAP, individuals are able to request an opt out from the case note audit through their NHS Trust. These requests are still honoured as part of the NCAP and would by extension remove the individual in question from the EXTEND Study, but (for the purposes of simplicity) is not an advertised method for opting out of the EXTEND study.

The CAG did not consider the privacy notice to be sufficient on its own as a notification mechanism. The CAG would like a separate patient notification document to be created, written in plain English, which clearly explains both the National Data Opt-Out and the local opt-out mechanisms. In addition, the CAG were unclear why the Pennine Trust Logo was included in the header.

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.

Whilst not specific to this project, Patient and Public Involvement has been conducted with service users for two other NIHR studies, in regard to the linkage of administrative data specifically for the improvement of EIP services. Both projects had regular Patient and Public Involvement meetings to discuss the appropriateness of de-identified patient data access, data linkage, and data security.

The Patient and Public Involvement referred to in the application refers to a separate research project based at the Oxford Department of Psychiatry (19/CAG/0092). This project tested the acceptability of using linked confidential patient data without consent. The group consisted of 6 individuals, who met with Dr Daniel Whiting in a 1:1 meeting (for one individual) and a group meeting (for the remaining 5) on 25th September and

30th September 2020 respectively. The group were recruited in collaboration with the NIHR Oxford Biomedical Research Centre, Oxford cognitive health Clinical Research Facility and Oxford Health NHS Foundation Trust. This group discussed the exceptional nature of accessing data without consent, were reassured by the specific data security measures in place for that study and considered that the “ends justified the means” in something like this.

This study includes two Patient and Public Involvement co-investigators; one with lived experience of EIP, and the other a carer. They are integrated within the team and have contributed to development and running of the study. They have been involved throughout, have attended all study co-investigator meetings and additional PPI-specific meetings.

The applicant explained that during the study period, the two Patient and Public Involvement co-investigators will be supported by a Patient and Public Involvement lead who will coordinate Patient and Public Involvement activities and a 5-person patient and carer EXTEND Involvement Group (EXTEND-InG). The InG is currently being recruited by the Patient and Public Involvement co-investigators, with support from other members of the study team.

Patient and Public Involvement activities during the study will include the InG meeting 3 times per year, assisting in identifying important factors of EIP to inform the creation of the causal model for the linked data study in WP2, commentary on all study outputs, and an online “town hall” style meeting at study commencement and closure, open to the wider community of people and families with experience of EIP services, to share research plans and seek feedback.

The CAG felt that the Patient and Public Involvement conducted to date was not overly relevant to the study in question. The Members felt that the additional proposed Patient and Public Involvement activities were strong, but needed to commence before the study began.

Exit strategy

The applicant has stated that once NHS Digital has linked the data, it will be de-identified by replacing the identifiers with a pseudonymisation key generated by the

Royal College of Psychiatrists. It is at this point that 's251' support can end. The application process will take around 3 months (on average) to gain approval and then the data linkage/production/dissemination is currently subject to a 12 week delay. However if full date of death is included in this dataset, then it cannot be defined as pseudonymised.

The CAG felt that, given that full date of death, which is considered to be confidential patient information for the purposes of the common law duty of confidentiality, was being collected for analysis, the length of support required, and the exit strategy were not clear. The CAG wished to know the length of support required by the applicant and for what purposes.

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. Please clarify if full date of death could be redacted to month and year of death in order to conduct the data analysis.

2. Please confirm the length of support required, depending upon whether full date of death is redacted prior to analysis or not.

3. Please provide a patient notification document, which clearly explains both the National Data Opt-Out and the local opt-out mechanisms.

4. Please confirm that the additional proposed Patient and Public Involvement will commence before the study begins, and provide evidence of this.

Specific conditions of support (Provisional)

The following sets out the specific conditions of support.

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

1. 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 20/21 DSPT review for **Royal College of Psychiatrists** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 16 May 2022)

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

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

Context

Purpose of application

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

Lifetime hormonal exposure is an important factor in many female cancers. Such factors include the timing of menstruation, pregnancy history, age at menopause, as well as use of oral contraceptives and hormone replacement therapy. For those experiencing difficulty conceiving, it is uncertain whether the medical conditions underlying

subfertility, and/or the treatments used to aid conception, also alter risk. It is also uncertain whether the babies so conceived are at altered risk of childhood cancer. This study aims to investigate this.

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

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

Confidential patient information requested

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

Cohort	7000 women who were investigated for a subfertility problem between 1973-89, identified from; • records of infertility clinics in Oxfordshire and West Berkshire • maternity records held by the Oxford Record Linkage Study (ORLS) (definition of subfertility - failure to conceive despite adequate attempts to do so for up to 1 year, at the time of their initial infertility clinic consultation)

	Data already extracted between 1992 and 2000 by the research team.
Data sources	6. University of Oxford linked database of women as described above, linked to outcome data received until 2013 (from ONS NHSCR). – obtained under 's251' support as part of NHSCR application (ECC 2-04(c)/2010).
Identifiers retained, and required for processing in order to anonymise the dataset	15. Womens' forenames (and initials), 16. Womens' surnames at birth and subsequently, 17. Date-of-birth 18. Gender 19. NHS numbers 20. Hospital numbers 21. unique study number 22. Data received from NHS Digital up until 2013; a. Cancer Registration data b. Mortality records, c. records of embarkation and exit/re-entry to the NHS
Identifiers required for analysis purposes	13. N/A – applicant states analysis will be undertaken on an anonymous dataset

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 were assured that this activity was in the public interest. The Members clarified that although 's251' support cannot be provided for retrospective activity, they

were content to recommend ‘s251’ support for ongoing retention, as the Members felt that it was in the public interest for the data to be accessed in order for the research to be completed.

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**

Applicant reasons that in order to consent, they would need to trace the 7000 women, some of whom have died, emigrated etc, and they state this would not be practical or possible due to lack of resources. Applicant does not retain addresses and reasons that to collect addresses would now be an additional disclosure that would also require ‘s251’ support. The CAG accepted this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to be viewed during the process of anonymisation. The applicant is anonymising the dataset as soon as practicably possible. The Members agreed there 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 privacy notice has been provided, which does have a local opt out option. This privacy notices will be displayed within NDWRH and on its website. It is not possible to apply the national data opt out, as the applicant is based at a university and will therefore not have access to the software that applies this in Healthcare organisations, the data has already been collected, and no further linkages are planned to be undertaken with NHS Digital.

The CAG were content with the opt out methodology. However the Members commented that the privacy notice provided was not very accessible to the lay person, and not very clear. The Members suggested this should be split into a layered format, of a short patient notification, which could then link on to a longer GDPR style privacy notice for those that wanted to read more. The new patient notification should be more accessible, with clear descriptions of which processing happened historically, and what is happening now, with 's251' as a legal basis under common law. It should be clear to the individuals reading it who the cohort is, in order for affected individuals to be able to opt out if they wish. The CAG suggested that the newly developed patient notification should be reviewed by a patient and public involvement group, in order to confirm that it is accessible to a lay audience.

The CAG noted that this notification will be displayed in clinical areas in the Nuffield Department of Women's and Reproductive Health, which is part of the Hospital, and also on its website. The Members agreed that this notification was therefore in the public domain.

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.

No patient and public involvement has been undertaken on the process that applicants now wish to undertake, as the applicant reasons that this is because they can't contact any of the cohort.

The Members were agreed that patient and public involvement can however be undertaken with a representative sample, and does not need to be undertaken with individuals involved in the actual research study. Therefore the applicant is required

to undertake some patient and public involvement with a representative cohort of individuals, to discuss the acceptability of this use of confidential patient information without consent. The patient and public involvement group should also review the newly developed patient notification materials, and consider if there are any other notification methods that may be appropriate, other than the clinical areas and the website.

Exit strategy

The exit strategy is anonymisation. The applicant estimates the data will be anonymised 3-6 months after 's251' support provided. The Members were content with this exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further 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 develop a layered patient notification, which is more clear and accessible to lay people, using the guidance in this letter.

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

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

Specific conditions of support (Provisional)

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 **20/21** DSPT review for **University of Oxford Medical Sciences Division (8HM11)** was confirmed as ‘**Standards Met’** on the NHS Digital DSPT Tracker (checked 08 June 2022)

As per our website, https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants/update-dspt-assurances-england/, CAG will be accepting 20/21 DSPTs until 12th August. Therefore the applicant is advised to request a review of the 21/22 DSPTs from NHS Digital, as this is a provisional outcome and full support may be granted after this date, depending on the applicant response to provisional outcome. Please see the section below headed security assurance requirements.

5. Minutes of the meeting held on 28th April 2022

The minutes of the meeting held on 28th April 2022 were not reviewed as the minutes have not yet been completed.

6. Any other business

No other business was raised.

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

Signed – Chair		Date
Dr Patrick Coyle, CAG Vice Chair & Ms Clare Sanderson, CAG Alternate Vice-Chair		*01 August 2022*
Signed – Confidentiality Advice Team		Date
Ms Caroline Watchurst, HRA Confidentiality Advisor		*18 July 2022*