Minutes of the meeting of the Confidentiality Advisory Group

10 November 2022 via Zoom

Present:

Name	**Role**
Dr Murat Soncul (AVC)	CAG Alternate Vice Chair
Ms. Clare Sanderson (AVC)	CAG Alternate Vice Chair
Mr David Evans	CAG Member
Mr. Anthony Kane	CAG Member
Ms Rose Payne	CAG Member
Mr Dan Roulstone	CAG Member
Ms Diana Robbins	CAG Member
Dr Sandra Duggan	CAG Member
Dr Harvey Marcovitch	CAG Member

Also in attendance:

Name	**Position (or reason for attending)**
Ms Katy Cassidy	HRA Confidentiality Advisor

Mr Will Lyse	HRA Approvals Administrator
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Mr Keith Berelowitz	REC Vice Chair (Observer)
Tamsin Destrube	HRA Business Improvement Operation Manager (internal observer)
Suzanne Hartley	(DARS), Business and Operational Delivery Manager, Data Access Team Manager - NHS Digital (Observer)
Jodie Taylor-Brown	(DARS), Case Manager, Senior Business and Operational Delivery Administrator - NHS Digital (Observer)
Professor Andrew Copas	Applicant role (attended for discussion of item 3a only)
Professor Laura Shallcross	Applicant role (attended for discussion of item 3a only)
Dr Oliver Strirrup	Applicant role (attended for discussion of item 3a only)

1. Introduction, apologies, and declarations of interest

CAG members Professor Lorna Fraser, Dr Pauline Lyseight-Jones and Mr Umar Sabat gave apologies.

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 has not yet provided a response to the advice provided by the CAG in relation to the **06 October 2022** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **06 October 2022** meeting applications.

3. Applications

a. 22/CAG/0165 - Shaping care home COVID-19 testing policy: A pragmatic cluster randomised controlled trial of an intervention to promote regular, asymptomatic testing in care home staff.

Purpose of application

This application from University College London set out the medical purpose of this research, namely, to investigate the feasibility, effectiveness and cost-effectiveness of regularly testing care home staff for COVID-19 to protect residents from severe infection and prevent outbreaks. This is an important question for policymakers, residents, care home staff and providers because testing impacts heavily on each of these groups in different ways. There is a unique, finite opportunity to determine whether regular COVID-19 testing in staff is worthwhile. Engagement work with providers and care home staff has shown that the issue of testing in staff is of major importance to them. This application is funded by NIHR HSDR and UKHSA.

At the start of the pandemic, policymakers' priority was to reduce deaths, severe illness and hospital admissions. The strong link between rates of infection in the community and risk of outbreaks and severe outcomes in care home residents justified the use of staff testing to prevent infection from the community. However, most residents are now fully vaccinated (90% have received 4th dose booster vaccination), and many have been infected, which substantially reduces their risk of COVID-19 related severe outcomes. Providers' main concern is that regular testing increases the risk of unnecessary care home closures due to minor outbreaks, impacting on business continuity (loss of income from new admissions) and residents' wellbeing (e.g. restrictions on visits). Based on current evidence, it is unclear whether regular

testing will increase or reduce the frequency of outbreaks. Two years into the pandemic, there remains a complete lack of evidence on whether the benefits of regular testing for COVID-19 outweigh its harms and under which scenarios.

280 participating care homes are randomised to 2 arms. The intervention arm will receive multi-component testing intervention (regular asymptomatic testing of staff for COVID-19 using LFTs combined with support payments for staff who test positive), and the control arm will follow national testing policy in place at the time. The applicant requires 's251' support for 2 elements of the application. Identifiable information regarding care home residents who are admitted to hospital during the testing period will be disclosed from the care homes to NHE England, who will link these data to the NHSE Foundry (COVID-19 datastore), which includes data on COVID-19 test results, vaccination status, hospital admissions and deaths. Additionally, identifiable information (name, DOB, NHS number, sex, postcode and CQC identifier) will be disclosed alongside any COVID-19 test taken by staff members or patients at participating care homes during the trial period, from care homes to NHS England COVID-19 testing portal. This flow does not require 's251' support, as this is undertaken as part of usual clinical care. Regarding patients, 's251' support is required for NHSE to link these data to the NHSE Foundry (COVID-19 datastore), which includes data on COVID-19 test results, vaccination status, hospital admissions and deaths. Regarding staff, 's251' support is required for NHSE to link to the NHSE Foundry (COVID-19 datastore) but only to provide the applicant pseudonymised data on the result of the COVID-19 test taken by the staff member. No outcome data is required for staff. These data will then be pseudonymised before being provided to the research team at UCL for analysis.

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

Confidential patient information requested

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

Cohort	All staff and residents in participating care homes during the study testing period 01 December 2022 – 31 March 2023. However, it is possible that the testing period may be extended. Applicants estimate this will include approximately 15,400 staff (55 per home) and 9,800 residents (35 per home).
Data sources	1. 280 participating care homes records (from the following providers): • Four Seasons Healthcare(FSHC)

	• HC-One • Orders of St John Care Trust (OSJCT) 2. NHS England – COVID-19 datastore (containing COVID-19 test results, vaccination status, hospital admissions and deaths from residents and staff who are in care homes that are participating in the trial. These routine datasets are already held by NHSE in the COVID-19 Datastore)
Identifiers required for linkage purposes	Residents who are admitted to hospital during the testing period: 1. NHS number 2. Name 3. Date of birth 4. Sex (derived from CQC-ID) 5. Postcode (derived from CQC-ID) Plus all patients and staff who are tested for covid during the trial period; 1. NHS number 2. Name 3. Date of birth 4. Sex (derived from CQC-ID) 5. Postcode (derived from CQC-ID)
Identifiers required for analysis purposes	1. N/A – data will be pseudonymised (effectively anonymised) for analysis
Additional information	The pseudonymisation key will be held by NHSE which is where the routine data is held within the COVID Datastore

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 were supportive of this application, and agreed this was in the public interest.

Scope

The CAG clarified the scope of ‘s251’ support required with the applicant during the meeting and were content that ‘s251’ support was required for the flows described in the application.

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**

Regarding staff members, the applicants reasoned in the application that It is not feasible to obtain informed consent from every staff member because there are large numbers of staff in participating homes, and staff turnover is high. This high turnover in conjunction with the large number of care homes that will be involved in the trial mean that it is not feasible to obtain individual consent from staff to enable usage of their data. In addition, it is important that applicants can obtain results from all staff who are tested, since partial data would undermine the ability to interpret compliance with testing. The applicant confirmed this as part of the discussions in the meeting, and the CAG were content to accept this justification.

Regarding care home residents, the applicant reasoned in the application that it is not feasible to seek individual-level consent from residents for use of these data. Many residents (up to 70%) have cognitive impairment which makes it very challenging to obtain informed consent from them, and there are substantial barriers to identifying nominated / personal consultees which means it is also highly unlikely that consultee advice could be provided. As hospital admissions are the primary outcome for the trial, it is critical to obtain complete and accurate data on this outcome to ensure trial findings are robust. As ‘s251’ support cannot be used to override the Mental Capacity Act, CAT queried why consent is not practicable, without only reasoning that it is due to a lack of care home resident’s capacity to consent. This was also put to the applicant in the meeting discussion. The applicant explained that as hospital admissions are the primary outcome, applicants would need to take consent or consultee advice for every care home resident, prior to whatever hospital admissions occurred. Full ascertainment is required, therefore data on all residents is required for the validity of the results. It is important that the final data from this study is representative of the mix of people who reside in care homes, in order for it to provide relevant results. The Members accepted these justifications.

- **Use of anonymised/pseudonymised data**

It would not be possible to undertake this study with fully anonymised data because it is not possible to link data without confidential patient information. The CAG accepted

that anonymous data was not a practicable alternative, and additionally the applicant is already receiving an effectively anonymous dataset, and so has minimised the identifiability of the data where possible.

'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.

Data collected from staff in this context is confidential patient information, as it is related to their health records. A staff poster regarding the collection of their testing data has been provided, with an opt out option. However, it does not mention any breach of confidentiality or the use of 's251'.

A patient/family poster has also been provided, that includes an opt out option, but it is less obvious than the staff opt out, and also implies data is anonymised at all times. Nor does it mention any breach of confidentiality or the use of 's251'.

Leaflets for both staff and patients have also been provided. An FAQ document for care homes has been provided. Additionally, a longer data information sheet has been provided, however it is not clear where this would be displayed, and also doesn't mention any flow of confidential patient information requiring 's251' support. (ie. those that were admitted to hospital/linkage). It also states that data is collected from HES etc, but the applicant has confirmed it is only being linked to the foundry, retained by NHSE.
The applicant stated that staff members can 'opt out' of regular testing and staff and residents can opt out of linkage of data within the foundry, and opt out details would be provided to NHSE so that the linkage within the NHSE foundry would not be undertaken regarding anyone who had opted out. The National Data Opt Out will be applied

The Committee were pleased that a QR code was included on the poster but noted that some care home residents may not have access to a smart phone, and requested the website text to be written out in addition. The Members also requested that the other notification materials need revising for clarity – for example, it was noted that one leaflet made reference to 'taking part' which sounds more in line with being invited to consent, rather than an application that required a CAG application. The CAG also felt that the uses of confidential patient information were not clearly stated, (ie. the linkage within NHSE, and the flow of care home residents data regarding those who were admitted to hospital), 's251' as a legal basis under common law and the fact the study has been through CAG is not mentioned, and the opt out options are not clear, either a study specific opt out, nor the fact that the National Data Opt Out will be applied. Specifically regarding the flow of data from care homes to NHSE about patients who

have been admitted to hospital, the applicant is clear they are happy to operate an opt out option, but this element is not clear on the patient posters and leaflets provided.

The Members discussed the notification materials with the applicant in the meeting. The applicant agreed that they could include a website link in addition to the QR code on the poster, and also suggested providing paper documentation in care homes. The CAG discussed the clarity of the notifications with the applicant and queried whether a patient and public involvement group had reviewed them. The applicant stated that the original VIVALDI study posters were shown to care homes, and suggested they could do the same for VIVALDI-CT. There is a care home meeting planned for the 22 November, and the applicants will plan to present the improved notification materials at this meeting, for feedback from care home residents.

Patient and Public Involvement and Engagement

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

As part of the application, the applicant explained they held three workshops (28 September, 3 October and 4 October 2022) with a total of 15 members of care home staff directly responsible for the care of residents to explore the feasibility of an asymptomatic testing trial in care homes. For the main VIVALDI study, team members spoke to eight care home staff for approximately 45 mins to explore their experiences of taking part in VIVALDI and on data sharing for research in general. The aim of these discussions was to hear how staff felt about sharing their pseudonymised data without consent for the purpose of research, however this is more specifically about the main VIVALDI study rather than VIVALDI-CT, and mentioned pseudonymised data rather than the use of confidential patient information.

The Members felt that staff were only part of the cohort for this study, and that there was minimal information provided about consultations with care home residents and nominees, about the use of confidential patient information without consent.
The Committee discussed with the applicant regarding if any patient and public involvement had been undertaken with care home residents. The applicant explained that they have been visiting care homes and asking families to come in and speak about research and the uses of data, but that it has been quite challenging, as often the care home managers are the gateway to being able to engage with patients, and this can tend to become a bottleneck, and also potentially biased towards residents who have positive feelings towards research, as these are the people who often volunteer to be spoken to and are engaged. The applicant acknowledged that reaching patients and the public who represent all care home residents is very difficult, and the CAG understood this explanation.

Despite the difficulties so far, the applicant explained that they plan to create a patient and public involvement group for the project, that will be made up of eight individuals including care home residents and families, with a focus on diversity. Across the study, the applicants plan to hold four workshops with twenty different stakeholders, including

care home residents, family members, staff, and providers, and will include the use of confidential patient information without consent in these discussions. The applicant also described links with The Outstanding Society, a Community Interest Company, who are working in partnership with providers about how to present information to care home residents. The CAG also suggested that there are other options of groups to go to, for example the Relatives and Residents Association, or carers groups, who may be happy to provide lay opinions on this use of confidential patient information without consent.

The CAG agreed that their impression was that the applicant was committed to involve and appropriately inform care home residents about this project, and that in the interests of the time limited window in which this study needs to begin to provide useful results, the Members were agreed that more patient and public involvement was not required prior to supporting the application, however a condition will be included to provide updates to CAG on the continuing work undertaken in this area.

Exit Strategy

UCL will receive pseudonymous datasets for analysis, alongside an NHSE COVID-19 datastore pseudo ID and are requesting 's251' support until 31 October 2023 in order to complete data collection and linkage.

Prior to the meeting, it was assumed that the exit strategy was only pseudonymisation, rather than anonymisation. This was because it was stated that the pseudonymisation key will be held by NHSE, alongside the COVID-19 Datastore. Applicant did not confirm when the key will be deleted by NHSE (implying it will be retained by NHSE for other projects), and therefore 's251' support would be required either until the point NHSE delete the key, or if the applicant removes the pseudo ID from the received dataset, then the dataset would be effectively anonymised, and no 's251' support required.

The exit strategy was discussed with the applicant in the meeting, and the applicant confirmed that it should be possible for NHSE to include a new pseudonymous ID that is specific for only this application, instead of providing the generic NHSE COVID-19 datastore pseudo ID. It was explained that some form of pseudo ID is required by the applicants, as there may be multiple data outputs relating to the same patient, that the applicants will need to know belong to one patient. The applicants stated there would be no key between the new pseudo ID and the NHSE ID, and therefore no way to re-identify and the data would be considered effectively anonymous. The applicant is to confirm this is possible, prior to 's251' support being provided, after discussing with NHSE as the data controller for the data.

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

Number	Action Required	Response from the applicant
1.	Please improve the notification materials, to include the following points; a. Include the website text alongside the QR code on the poster b. Ensure that the use of confidential patient information without consent is clearly described c. Ensure that the use of 's251' as a legal bass under common law is mentioned d. Ensure the opt out options are clear e. Present the revised patient notification materials to patients to ensure they are acceptable to lay people	
2.	Please confirm the exit strategy from 's251' support, regarding if a study specific pseudo ID will be applied by NHSE instead of the generic COVID-19 Datastore pseudo ID	

Specific conditions of support (Provisional)

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

1. Please provide feedback from the ongoing planned patient and public involvement, to ensure there is support from care home residents for this use of confidential patient information without consent. Please provide this to CAG as soon as it is available, but at the latest, six months from the date 's251' support is provided. If strong objections are noticed in ongoing patient and public involvement, please inform CAG of these immediately.

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

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

The NHS Digital **21/22** DSPT reviews **NHS England** was confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 18 November 2022)

Due to the number of organisations involved it is the responsibility of University College London, as controller, to ensure that participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

b. 22/CAG/0150 - United Kingdom Register of Stored Ovarian and Testicular Tissue

Purpose of application

This application from the University of Leeds set out the purpose of setting up a register of all stored ovarian and testicular tissue obtained from young people in the UK.

The UK Register of Stored Ovarian and Testicular Tissue (UKSTORE) will be the first registry of stored ovarian and testicular tissue collected from young people in the UK. The registry will be used to support service development, evaluation and research.

The data will be obtained from all centres where ovarian and testicular tissue were collected and stored from patients aged 0-24 years. Storage centres will identify eligible patients via clinical records and local databases, and the confidential patient information transferred to UKSTORE. Confidential patient information will be used to perform data linkage to extract relevant data from existing databases. Additional data will be collected from patient medical records, directly from patients and from their GP's.

UKSTORE data is divided into two main components; data captured without consent and data captured only with written informed consent. Data captured without consent comprises most data for UKSTORE. This is referred to as "core data" and includes confidential patient information. "Core" data will be captured for all patients who preserve tissue in the UK and are aged 0-24 when they do so. "Core" data will be captured for retrospective (who have already had tissue preserved) and prospective patients (who preserve tissue after UKSTORE has been established).

Data captured with informed written consent will only be sought from patients who are aged 16 years and above and is referred to as "additional data." This data is focused on reproductive outcomes. Patients aged 16 years and over in England will be invited to consent when they attend a follow up appointment, or at any other appointment as deemed appropriate by their clinical team. Patients who are no longer attending routine follow up appointments will be sent an approved UKSTORE information sheet about additional data capture and invited to contact the tissue storage centre or UKSTORE directly, to give informed consent. This information will be sent alongside the next

routine correspondence sent from tissue storage centres that confirms ongoing tissue storage. Storage centres will perform an additional safety check to screen and exclude patients they know have registered an opt out.

A recommendation for class 1, 2, 4, 5, 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 whose ovarian or testicular tissue was collected when they were aged 0-24 years. The timeframe for inclusion will go back to the first point at which tissue preservation began so that it includes all patients (whole population). Records in England go back to 2013.
Data sources	1. Patients clinical records, including regional paediatric, teenage and young adult cancer centres 2. NHS centres in the UK that store ovarian and testicular tissue harvested from people when they were aged 0- 24 years. 3. Patients (self-reported) 4. NHS Digital held datasets: a. Cancer registry b. Cancer pathway c. SACT d. RTDS e. HES admitted care f. National Disease Registration Service for patients with cancer, congenital anomalies and rare diseases (NCARDRS)

	g. National Cancer Registration Analysis Service (NCRAS) 5. GP data via GPES 6. External disease registries, including: a. The Welsh Cancer Intelligence & Surveillance Unit (WCISU) b. The European Society for Blood and Marrow Transplantation (EBMT) Registry. United Kingdom Primary Immunodeficiency (UKPID) Registry. c. The British Society for Paediatric and Adolescent Rheumatology (BSPAR). d. The National Haemoglobinopathy Registry (NHR).
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number 4. GP Registration 5. Date of birth 6. Date of death 7. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – unit level 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

However, the CAG noted concerns regarding the volume of data that was being collected through data linkage. The CAG requested that the applicant clarify the rational for collecting the large amount of participant data.

Access by third parties

Third parties could apply to use the data collected in UKSTORE for their own projects. The CAG asked the applicants to explain how they would ensure that the data would be used for medical purposes only.

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**

Many of the relevant patients would have been aged 0-16 years when their tissue was harvested. The applicants advised that they wished to avoid seeking consent to reduce the potential risk of causing distress and burden to patients. Around 80% of patients aged 0-24 years whose ovarian or testicular tissue is stored have a diagnosis of cancer and many patients will be receiving active treatment for their illness, while some patients will have been treated decades previously and will no longer be in active treatment. The data that UKSTORE will collect is captured as part of routine clinical care and will not have any impact on their treatment.

The applicants also seek to ensure that the data in the registry is as complete as possible.

Patients who consented to participate in the additional data collection would be actively engaging with the research.

The CAG agreed that it had not been clearly explained why consent for the core data collection could not be obtained at the same time as consent was sought for the additional data collection.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link data from NHS centres in the UK that store ovarian and testicular tissue to University of Leeds, onward disclosure to a number of organisations to enable the return of a linked dataset to University of Leeds.

The CAG was content that use of anonymous information was not a practicable alternative.

Justification of Identifiers

It is usual practice for identifiable patent information to be retained on a separate database to clinical data. However, it appeared that, in this application, both were retained in the same database and CAG requested justification for this approach, or confirmation that this was not happening.

'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.

Participants could opt out by informing their clinical team. They could also contact UKSTORE directly using the contact information given in the information leaflet or on the UKSTORE website. Furthermore, they could register an opt out request via the National Data Opt-Out (2018). Posters and leaflets were provided.

The CAG noted that when a patient opted-out, their core data would be anonymised rather than deleted and removed from the database. The CAG requested a justification into why the research team could not remove the data from the study. Members noted that if an individual requested to opt-out of the study, an option should be available to opt-out of all of their data being used for research purposes, rather than only their identifiable information being removed.

The CAG noted that there was no reference to section 251 in any of the patient notification materials. The CAG requested that an age appropriate reference to section 251 was included in all notifications.

The CAG noted that the opt-out process was hidden within the content of the notification. The CAG requested that the opt-out process was clearly displayed within the notification.

The Group noted an opt out form had been provided and were not clear if this would be used by the patients opting out or their clinician. If this is planned to be used by the patient, the CAG considered this was too unwieldy for an opting out patient to deal with, and requested the process be made easier for patients.

The CAG asked that the patient notification included a link to the website. A contact number and email need to be provided, as well the QR code.

The CAG noted that there was minimal information displayed on the website. The CAG queried whether the website would be updated in due course.

The CAG noted that the “Research database opt-out policy” document contained an incorrect reference to section 251 and the common law. Members asked that the standard CAG wording, given below, was included.

The application was reviewed by the Confidentiality Advisory Group (CAG). CAG is an independent group of lay people and professionals which provides expert advice on the use of confidential patient information without consent. CAG recommended that our application should be supported, and the Secretary of State for Health/Decision Maker within the Health Research Authority approved this.

Patient and Public Involvement and Engagement

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

Members of the public, including expert patients had been consulted. Participants were recruited via useMYdata, DATACAN, Leeds Research Owls, Candlelighters, Children's Cancer and Leukaemia Group and Teenage Cancer Trust. Eleven young people aged 11-18 and seven adults, including three parents of children who had undergone ovarian

or testicular tissue preservation, attended the consultations. Three 1.5-hour virtual meetings were used to explore views of data capture and data use for UKSTORE. Following an overview of UKSTORE aims and objectives, participants were asked to choose answers to multiple choice questions using Mentimeter web-based technology, the online chat function and/or verbal discussion.

Use of confidential patient information without consent was discussed during the PPIE meetings. The applicants provided a report on the engagement undertaken.

The CAG asked that the applicants continued to engage with the Patient and Public Involvement group. The applicants needed to ensure that the scale of the data collection and the volume of data involved were made clear to those consulted.

The CAG queried whether any lay representation was included in both the steering group and data release committee. If not, members asked for confirmation that lay members would be included in each group.

Exit strategy

The applicants sought to retain confidential patient information. Patients would be contacted for consent to collect the “additional data,” however there was a lack of clarity over the consent process and whether consent was the exit strategy for patients from whom consent was sought

The CAG noted that patients who died before consent could be taken would be included under section 251 support. However, after some time had passed, no further information and further data linkages could be undertaken for deceased patients. Members asked whether the confidential patient information for deceased patients could be deleted once no further data could be collected, providing an exit strategy from support for this group.

The CAG requested clarification on who completed the dissent form, whether this was the treating clinician or the patient.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Provide a rationale for collecting the large quantity of participant data sought.

2. Provide details on how it will be ensured that third parties applying to use the UKSTORE dataset will use the data for medical purposes only.

3. Clarify why consent for core data could not be obtained at the same time as consent was obtained for additional data.

4. Justify why the identifiers and clinical data are held within the same database.

5. Justify why the research team could not remove the data from the study instead of anonymisation, should patients opt-out of use of their data.

6. The patient notification materials need to be revised as follows:
    a. The explanation of the CAG role and section 251 needs to be included, as given above.
    b. The opt-out process needs to be clearly described and made obvious in the notification materials.
    c. A link to the website information, and telephone and email contacts need to be included.

7. Please clarify the use of the opt out form, and if this is planned for patient use, please consider removing this form from the process to make it easier for patients to opt out.

8. Clarify whether the website was to be updated in due course.

9. Continue engagement with the Patient and Public Involvement group and provide the CAG with feedback from discussion of the volume of data collected.

10. Increase lay representation in both the steering group as well as data release committee.

11. Please clarify on the long-term exit strategy, including whether the confidential patient information for deceased patients would be deleted once no further information could be collected.

12. Clarify who completes the dissent form, whether this is done by the patient or the treating clinician.

Specific conditions of support (provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Favourable issued 20 September 2022**

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

   Due to the number of participating sites 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/0153 - United Kingdom Register of Stored Ovarian and Testicular Tissue (non-research)

Purpose of application

This non-research application from the University of Leeds set out the purpose of setting up a register of all stored ovarian and testicular tissue obtained from young people in the UK.

The UK Register of Stored Ovarian and Testicular Tissue (UKSTORE) will be the first registry of stored ovarian and testicular tissue collected from young people in the UK. The registry will be used to support service development, evaluation and audit, as well as research, for which a separate application has been submitted.

The data will be obtained from all centres where ovarian and testicular tissue were collected and stored from patients aged 0-24 year. Storage centres will identify eligible patients via clinical records and local databases, and the confidential patient information transferred to UKSTORE. Confidential patient information will be used to perform data linkage to extract relevant data from existing databases. Additional data will be collected from patient medical records, directly from patients and from their GP's.

UKSTORE data is divided into two main components; data captured without consent and data captured only with written informed consent. Data captured without consent

comprises most data for UKSTORE. This is referred to as “core data” and includes confidential patient information. “Core” data will be captured for all patients who preserve tissue in the UK and are aged 0-24 when they do so. “Core” data will be captured for retrospective (who have already had tissue preserved) and prospective patients (who preserve tissue after UKSTORE has been established).

Data captured with informed written consent will only be sought from patients who are aged 16 years and above and is referred to as “additional data.” This data is focused on reproductive outcomes. Patients aged 16 years and over in England will be invited to consent when they attend a follow up appointment, or at any other appointment as deemed appropriate by their clinical team. Patients who are no longer attending routine follow up appointments will be sent an approved UKSTORE information sheet about additional data capture and invited to contact the tissue storage centre or UKSTORE directly, to give informed consent. This information will be sent alongside the next routine correspondence sent from tissue storage centres that confirms ongoing tissue storage. Storage centres will perform an additional safety check to screen and exclude patients they know have registered an opt out.

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

Confidential patient information requested

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

Cohort	Patients whose ovarian or testicular tissue was collected when they were aged 0-24 years. The timeframe for inclusion will go back to the first point at which tissue preservation began so that it includes all patients (whole population). Records in England go back to 2013.
Data sources	1. Patients clinical records, including regional paediatric, teenage and young adult cancer centres

	2. NHS centres in the UK that store ovarian and testicular tissue harvested from people when they were aged 0- 24 years. 3. Patients (self-reported) 4. NHS Digital held datasets: a. Cancer registry b. Cancer pathway c. SACT d. RTDS e. HES admitted care f. National Disease Registration Service for patients with cancer, congenital anomalies and rare diseases (NCARDRS) g. National Cancer Registration Analysis Service (NCRAS) 5. GP data via GPES 6. External disease registries, including: a. The Welsh Cancer Intelligence & Surveillance Unit (WCISU) b. The European Society for Blood and Marrow Transplantation (EBMT) Registry. United Kingdom Primary Immunodeficiency (UKPID) Registry. c. The British Society for Paediatric and Adolescent Rheumatology (BSPAR). d. The National Haemoglobinopathy Registry (NHR).
Identifiers required for linkage purposes	1. Name 2. NHS Number

	3. Hospital ID number 4. GP Registration 5. Date of birth 6. Date of death 7. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – unit level 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the 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 medical purpose and was in the public interest.

However, the CAG noted concerns regarding the volume of data that was being collected through data linkage. The CAG requested that the applicant clarify the rational for collecting the large amount of participant data.

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**

Many of the relevant patients will have been aged 0-16 years when their tissue was harvested. The applicants advised that they wished to avoid seeking consent to reduce the potential risk of causing distress and burden to patients. Around 80% of patients aged 0-24 years whose ovarian or testicular tissue is stored have a diagnosis of cancer and many patients will be receiving active treatment for their illness, while some patients will have been treated decades previously and will no longer be in active treatment. The data that UKSTORE will collect is captured as part of routine clinical care and will not have any impact on their treatment.

The applicants also seek to ensure that the data in the registry is as complete as possible.

Patients who consented to participate in the additional data collection would be actively engaging with the research. The CAG agreed that it had not been clearly explained why, for these patients, consent for the core data collection could not be obtained at the same time as consent was sought for the additional data collection.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link data from NHS centres in the UK that store ovarian and testicular tissue to University of Leeds, onward disclosure to a number of organisations to enable the return of a linked dataset to University of Leeds.

The CAG was content that use of anonymous information was not a practicable alternative.

Justification of Identifiers

It is usual practice for identifiable patent information to be retained on a separate database to clinical data. However, it appeared that, in this application, both were retained in the same database and CAG requested justification for this approach, or confirmation that this was not happening.

'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.

Participants could opt out by informing their clinical team. They could also contact UKSTORE directly using the contact information given in the information leaflet or on the UKSTORE website. Furthermore, they could register an opt out request via the National Data Opt-Out (2018). Posters and leaflets were provided.

The CAG noted that when a patient opted-out, their core data would be anonymised rather than deleted and removed from the database. The CAG requested a justification into why the research team could not remove the data from the study. Members noted that if an individual requested to opt-out of the study, an option should be available to opt-out of all of their data being used for research purposes, rather than only their identifiable information being removed.

The CAG noted that there was no reference to section 251 in any of the patient notification materials. The CAG requested that an age appropriate reference to section 251 was included in all notifications.

The CAG noted that the opt-out process was hidden within the content of the notification. The CAG requested that the opt-out process was clearly displayed within the notification.

The Committee noted an opt out form had been provided and were not clear if this would be used by the patients opting out or their clinician. If this is planned to be used by the patient, the CAG considered this was too unwieldy for an opting out patient to deal with, and requested the process be made easier for patients.

The CAG asked that the patient notification included a link to the website. A contact number and email need to be provided, as well as the QR code.

The CAG noted that there was minimal information displayed on the website. The CAG queried whether the website would be updated in due course.

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.

Members of the public, including expert patients have been consulted. Participants were recruited via useMYdata, DATACAN, Leeds Research Owls, Candlelighters, Children's Cancer and Leukaemia Group and Teenage Cancer Trust. Eleven young

people aged 11-18 and seven adults, including three parents of children who had undergone ovarian or testicular tissue preservation, attended the consultations. Three 1.5-hour virtual meetings were used to explore views of data capture and data use for UKSTORE. Following an overview of UKSTORE aims and objectives, participants were asked to choose answers to multiple choice questions using Mentimeter web-based technology, the online chat function and/or verbal discussion.

Use of confidential patient information without consent was discussed during the PPIE meetings. The applicants provided a report on the engagement undertaken.

The CAG asked that the applicants continued to engage with the Patient and Public Involvement group. The applicants needed to ensure that the scale of the data collection and the volume of data involved were made clear to those consulted.

Exit strategy

The applicants sought to retain confidential patient information. Patients would be contacted for consent to collect the “additional data,” however, as mentioned above, there was a lack of clarity over the consent process and whether consent was the exit strategy for patients from whom consent was sought.

The CAG noted that patients who died before consent could be taken would be included under section 251 support. However, after some time had passed, no further information and further data linkages could be undertaken for deceased patients. Members asked whether the confidential patient information for deceased patients could be deleted once no further data could be collected, providing an exit strategy from support for this group.

The CAG requested clarification on who completed the dissent form, whether this was the treating clinician or the patient.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Provide a rationale for collecting the large quantity of participant data sought.

2. Clarify why consent for core data could not be obtained at the same time as consent was obtained for additional data.

3. Justify why the identifiers and clinical data are held within the same database.

4. Justify why the research team could not remove the data from the study instead of anonymisation, should patients opt-out of use of their data.

5. The patient notification materials need to be revised as follows:
    a. The explanation of the CAG role and section 251 needs to be included, as given above.
    b. The opt-out process needs to be clearly described.
    c. A link to the website information, and telephone and email contacts need to be included.
6. Please clarify who completes the opt out form. If this is completed by the patient, please consider removing this form from the process.

7. Clarify whether the website was to be updated in due course.

8. Continue engagement with the Patient and Public Involvement group and provide the CAG with feedback from discussion of the volume of data collected.

9. Please clarify on the long-term exit strategy, including whether the confidential patient information for deceased patients would be deleted once no further information could be collected.

Specific conditions of support (provisional)

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

1. 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:**

   Due to the number of participating sites 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

d. 22/CAG/0151 - Collaboration on Prevent In-Place Extremism Referrals

Purpose of application

This application from Birmingham and Solihull Mental Health Foundation Trust set out the purpose of creating a research database for the purpose of analysing the full cohort of referrals to the West Midlands Prevent-in-Place (PiP) team.

The applicants seek to develop a database to be used in a programme of research to conduct a detailed analysis of referrals to the West Midlands Prevent-in-Place (PiP) team. The database is a collaboration between Birmingham and Solihull Mental Health Foundation Trust, West Midlands Police and University College London. The database will be used to answer questions about the mental health needs experienced by those managed within Counter Terrorism (CT) policing, service gaps or barriers and outcomes for those supported by mental health services.

Eligible patients will be identified from the West Midlands PiP, held at Birmingham and Solihull Mental Health Foundation Trust (BSMHFT). Confidential patient information will be disclosed to University College London, for linkage to data from the Prevent Case Management Tracker System (PCM Tracker). The data from the PCM Tracker is outside the scope of support as this is not confidential patient information. Research staff will input the data into an excel spreadsheet where it will be anonymised before use in analysis.

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

Confidential patient information requested

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

Cohort	Individuals referred to the Prevent In-Place (PiP) Service from 2016 to the present. Active cases and individuals that have opted out of NHS research will have been removed.
Data sources	1. Confidential patient information held in Prevent-in-Place (PiP) records, held at Birmingham and Solihull Mental Health Foundation Trust (BSMHFT). 2. CT Policing - Prevent Case Management Tracker System (PCM Tracker) – out of the scope of support as this does not contain confidential patient information.
Identifiers required for linkage purposes	1. Postcode – district level 2. Age 3. Gender
Identifiers required for analysis purposes	1. Postcode – district level 2. Gender 3. Occupation 4. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

To enable support under the Regulations to be provided, the activity must have a medical purpose as defined in s251 (12) of the NHS Act 2006. Following review, it is unclear from the application that the application has a medical purpose, as much of

the objectives outlined in the application seem to relate to crime prevention/counter terrorism aims. The Committee noted that the medical purposes detailed in the response to Confidentiality Advice Team (CAT) queries were listed as;

Developing a research database which can be used to answer a range of empirical questions, including;

1) What are the mental health (MH) needs experienced by individuals managed within CT policing. Have these changed over time?
2) Are particular MH needs associated with specific counter terrorism vulnerabilities or behaviours
3) What are the subgroups with regards to mental health and other complex needs
4) What are the service gaps or barriers to engaging with mental health services.
5) What are the outcomes for individuals supported by mental health services

However, these need to be expanded and further examples of medical purpose provided, as the Members were currently not in agreement that this application had an association with healthcare. The CAG therefore requested confirmation that this activity represented a medical purpose, by providing clarity on the health outcomes the study is looking at and how the research would be beneficial to patients.

Practicable alternatives

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

- **Feasibility of consent**

The applicants advised that consent was not feasible as not all those referred to West Midlands Prevent-in-Place were aware that they were referred. Alerting individuals to their referral could cause distress or safeguarding issues, either to themselves or others.

West Midlands Prevent-in-Place also did not update contact details for those who have been discharged from the service.

The CAG was content that consent was not a feasible option.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required to allow research staff to identify suitable patients and link to data from the Prevent Case Management Tracker System.

Trust staff did not have the capacity to undertake the data extraction. The applicants advised that Birmingham and Solihull Mental Health Foundation Trust and University College London research staff would require access to confidential patient information whilst undertaking the data extraction. Anonymised data would be entered into an excel spreadsheet and cases would be allocated a reference number.

CAG was content that using anonymous information was not a practicable alternative.

'Patient Notification' and mechanism for managing dissent

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

Birmingham and Solihull Mental Health Foundation Trust have a Privacy Notice on their website, which informs individuals that their data may be used for research and service evaluation purposes. This isn't specific to this application. The Privacy Notice had not been provided for review.

The applicants advised that it was not possible or appropriate to undertake patient notification due to the nature of the Prevent In-Place service. Some individuals may not be aware they have been referred to Prevent, e.g. if they have been referred by a family member and then quickly screened and exited out of Prevent. Alerting the individual may cause distress or potential safeguarding issues to them or others.

There may also be other reasons individuals are unaware they have been referred to CT policing e.g. they were associated with an investigation. Alerting them may cause operational issues for Counter Terrorism policing increasing the risk to individuals and the public.

The researchers or Prevent In-Place Team would not know whether patients were aware that that they had been referred to Prevent or to CT policing, or whether alerting them would present a police operational issue.

A communications plan had been developed. The intention is to publish the findings in high ranking peer reviewed journals. Findings will also be published on relevant police and health websites and via national media. Briefings will also be given to relevant stakeholders including health, CT Policing and the Home Office.

The Trust has an internal mechanism to check individuals against the National Data Opt-Out and this will be conducted prior to the research and relevant cases removed.

The CAG noted a lack of rationale given for not undertaking patient notification Members agreed that patient notification needed to be undertaken in order to meet both the CAG requirements for notification and to meet Articles 13 and 14 of GDPR. A communications strategy and patient notification materials needed to be provided in any resubmitted application. These materials also needed to explain how patients can dissent to use of their data.

Patient and Public Involvement and Engagement

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

The applicants explained that they had not undertaken any patient and public involvement. There was concern that sharing information about the study at this stage may cause alarm and impact negatively on individuals, affect engagement with Prevent and increasing the risk of terrorism to individuals and communities.

The three organisations involved in the study have developed a communications strategy which will be initiated when the database has been completed and there are some initial findings to share. The research will be published in high impact journals and professional publications. Comprehensive details of the research and the initial findings will be shared with key stakeholders and the public via health and policing websites and engaging with mainstream media. Responses to a range of questions will be prepared and reviewed via appropriate channels and communications departments such as the purpose of the research, how the data has been processed and how the findings will be used.

The applicants have plans to engage with professional, patient, carer and public groups e.g. The Counter Terrorism Advisory Group (CTAG) to consider how the data and findings can inform and develop the service delivery for individuals vulnerable to being drawn towards terrorism.

The CAG noted the rationale given for not conducting patient and public involvement, however members agreed that the planned engagement with CTAG and/or other mental health charities and advisory groups could include discussion of the use of patient data without consent. Feedback from patient and public involvement would need to be provided in any resubmitted application.

Exit strategy

Once the data had been extracted from files, the database would be fully anonymised and would not contain confidential patient information.

The CAG was content with the exit strategy proposed.

Confidentiality Advisory Group advice conclusion

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

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

Further information required

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

1. Provide details on the study's medical purpose, including an overview of the health outcomes and how this research would be beneficial to patients.
2. A communications strategy and patient notification materials need to be provided. The materials need to explain how patients can dissent.
3. Patient and public involvement needs to be conducted with relevant mental health charities and advisory groups.

e. 22/CAG/0154 - Evaluating the clinical and cost-effectiveness of a conservative approach to oxygen therapy for invasively ventilated adults in intensive care

Purpose of application

This application from The Intensive Care National Audit & Research Centre (ICNARC) set out the purpose of medical research which aims to evaluate the clinical effectiveness of conservative versus usual oxygen therapy on 90-day all-cause mortality. The UK-ROX trial is a multi-centre randomised clinical trial (RCT), and has already begun without the need for a CAG application. However the applicants have submitted an amendment to the REC to introduce the need for 's251' support.

184,000 patients annually are admitted to NHS intensive care units (ICUs) and over 30% require a ventilator. Giving oxygen through the ventilator is essential. However, it is not known how much oxygen should be given to optimise recovery. Both too much, and too little oxygen may cause harm. This study will look at the effect of a small reduction in oxygen. Results will have a large and immediate impact on ICU clinical practice and on patient outcomes throughout the NHS. Data from the 16,500 patients in this study will also contribute to a larger global study of 40,000 patients. The global study will answer similar questions about oxygen therapy in ICU patients but from an international perspective.

The purpose of linkage to the Case Mix Programme national clinical audit of patients screened but not enrolled into UK-ROX, is to review whether certain subgroups of patients are being excluded, and to ensure equality, diversity and inclusiveness of the trial population.

The purpose of linking outcome data for participants from whom patient consent, or consultee opinion, was unable to be obtained, is because excluding data from these cohorts of patients may introduce substantial bias and impact upon the safety monitoring/reporting and, ultimately, the scientific validity of the trial and may prevent evidence of significant clinical benefit from being detected.

All patients will be unconscious at the time of treatment, as by definition they become eligible once mechanical ventilation has started, and therefore patients will be recruited under a research without prior consent (RWPC) model, in accordance with the Mental Capacity Act 2005. The applicants are seeking 's251' support to process confidential patient information for all patients from the end of the emergency event until patient death or until either patient consent or a consultee opinion is obtained. For non-survivors, support is needed for the collection of confidential patient information from the treating hospital, and linkage to ICNARC CMP, and NHS England (previously NHS Digital) and DHCW datasets. For surviving patients, confidential patient information will be collected until either the patient or a consultee explicitly refuses agreement to the processing of their confidential patient information. If the patient survives but the researchers are unable to contact the patient or a consultee to seek consent, support will also be needed to continue to collect confidential patient information and link to other data sources. This is in line with other applications of this type. In addition, the applicants require 's251' support to link data for those patients who were screened but not enrolled into the UK-ROX trial

to the CMP. This is undertaken with the ICNARC Case Mix Pro-gramme admission number, which is pseudonymous, disclosed to ICNARC from participating Trusts, however as applicants retain confidential patient information linked to the ICNARC CMP ID, and therefore have the ability to re-identify, 's251' support is also required for this disclosure and linkage.

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

Confidential patient information requested

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

Cohort	The study will include 16,500 patients from 100 UK NHS ICUs But 's251' support is only relevant to: patients receiving mechanical ventilation in participating critical care units who were screened but not enrolled to UKROX, ~53,000 patients And participants included in UKROX from whom patient consent, or consultee opinion, was unable to be obtained (e.g. because the patient died or was discharged prior to regaining capacity) ~300 patients.
Data sources	1. Participating ICU's (across England and Wales)– UK-ROX collected study data and secure electronic case report form 2. Intensive Care National Audit & Research Centre (ICNARC) - Case Mix Programme dataset 3. NHS Digital: a) Civil Registrations (deaths) dataset b) Hospital Episodes Statistics (HES) 4. Digital Health and Care Wales (DHCW) a) Patient Episodes Data for Wales (PEDW)

Identifiers required for linkage purposes	Regarding patients who were screened but not included in UK-ROX; 1. ICNARC Case Mix Programme admission number Regarding those included in UK-ROX but were discharged or died prior to consent or consultee opinion being obtained: 1. UK-ROX Trial ID 2. ICNARC Case Mix Programme admission number 3. NHS Number 4. date of birth 5. sex 6. postcode
Identifiers required for analysis purposes	1. Date of death 2. Gender 3. Ethnicity
Additional information	Linked extracts will be received quarterly.

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 was agreed this was in the public interest, commenting that appropriate diversity in the trial was important, and 's251' was required for this.

Scope

- International research

The CAG noted that data from the 16,500 patients in this study will also contribute to a larger global study of 40,000 patients. The global study will answer similar questions about oxygen therapy in ICU patients but from an international perspective. However, CAG were unclear on the scope of support required regarding this. The 's251' support requested covers 2 cohorts – one cohort of patients who were screened but not included in UK-ROX, and another cohort of patients included in UK-ROX from whom patient consent, or consultee opinion, was unable to be obtained. CAG assumed that the cohort of patients screened but not included in UK-ROX would not have any data shared internationally as they would not be considered a patient included in the study. The sharing of data collected under 's251' support would therefore only be relevant to the estimated 300 patients included in UK-ROX from whom patient consent, or consultee opinion, was unable to be obtained, as the remainder of the patents would be included in UK-ROX with consent as the legal basis under common law. The applicant is required to confirm this. The CAG were interested in what data would be shared, and also wished to confirm that only effectively anonymous data would be shared internationally regarding these individuals. 's251' support is not required for the flow of this data if it is effectively anonymous, but it is important that this purpose is clarified and listed as part of the application, as part of the data would have been collected with 's251' support.

- Non responders to consent

As part of this application, the applicant has requested 's251' support to allow the disclosure of confidential patient information, regarding UK-ROX participants for whom explicit patient consent, or consultee opinion was unable to be obtained, **and specifically did not respond to telephone or postal consent mechanisms**, from participating Trusts to ICNARC for the purposes of linkage with ICNARC CMP, and for the onwards disclosure of confidential patient information to NHS England (previously NHS Digital) and Digital Health and Care Wales (DHCW) for linkage with HES, ONS Mortality datasets, and PEDW, and for the flow of data back (as this contains Date of death).

The CAG has published specific guidance, managing-non-response-guidance-v1-2_Aplc9nj.pdf after discussion with the ICO, on their position regarding patients who are approached to consent by phone or letter, who then do not reply. The position from CAG is that if a patient is specifically approached to consent, and they do not respond to that approach, then non-response to consent must be accepted as dissent. Therefore, the CAG cannot provide 's251' support specifically for any subset of patients who have been discharged prior to consultee advice or consent being gained, if they were then specifically approached to consent, and did not reply.

The applicant currently states that if they fail to reach the participant by phone, or if there is no telephone number, a letter is sent asking for consent. The CAG reviewed this letter and stated that it does already say if no response is received, their data will be linked. However, the letter does also clearly ask for consent. The CAG advise that this letter could be altered to a patient notification document stating that linkage to outcome data would be undertaken with 's251' as the legal basis under common law, and give details of how the participant could opt out of this happening. The letter should also say the patient could call for further information, at which stage the patient could then be consented if they get in touch with the study team.

The CAG would like to clarify that the applicant does not have to assume dissent if a patient merely does not answer the phone, as no explicit invitation to consent would have been issued at this stage. If any further explanations are required regarding this, the applicant is advised to contact the Confidentiality Advice Team (CAT) in the first instance.

Practicable alternatives

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

- **Feasibility of consent**

Consent will be sought at the earliest opportunity. The justification for 'section 251' support is that not being able to include information from patients who have been included in the trial who die very soon after enrolment or are still very unwell (i.e. those who are discharged without capacity), will result in bias and could may make one of the treatments appear more beneficial than it actually is or hide any indications of harm caused. It is not possible to consent those who pass away or are discharged prior to regaining capacity. The CAG agreed with this justification, however wondered if it would be possible to seek consent at any clinical follow up by the initial treating clinician?

Justification was also provided for not consenting those who are screened but not randomised into UK-ROX. The applicant reasoned that these individuals will be very unwell at the time of arrival, and applicants confirm that due to the large number of potentially eligible patients screened, (~53,000), it is not practicable to approach for consent if/when they regain capacity. The CAG accepted this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage, and full date of death is required for analysis. Data is minimised where possible. The CAG was content that this using anonymised data was not a practicable alternative.

Data items

The CAG noted that sex is required for linkage, but gender is listed as required for analysis. Should sex be listed as required for analysis instead of gender? Noting this is possibly due to the CAG form options.

'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 Patient information sheet (PIS) and consent forms provided are not relevant for the CAG cohort - these have already been approved by the REC and are REC remit.

Regarding any patient notification that can be used for the CAG cohort, (ie, those patients that were screened but not included, and any individual who died or was discharged prior to consent or consultee advice being gained), the applicant has returned a poster and a leaflet for the relatives room. The applicant has also provided a privacy notice.

Applicants anticipate that some patients who have a National Data Opt Out (NDOO) in place will be enrolled to the trial, due to the emergency nature of the recruitment. Following enrolment, patients are approached for consent, and until this point, only pseudonymised data are collected for UK-ROX. Patient consent or consultee opinion, will overrule NDOO. For participants whom consent or consultee opinion was unable to be obtained, the NDOO will be applied by the participating site prior to disclosure to ICNARC, no identifiable data will be disclosed to ICNARC, and linkage with NHS England (previously NHS Digital) will not be undertaken. For linkage with NHS England (previously NHS Digital) data, patients who provided explicit consent/consultee opinion will be separated from those who are linked under 's251' - this will allow for the NDOO to be applied only to the records for patients without consent. For patients screened but not enrolled into the trial who are identified as having an NDOO in place, participating

sites will not enter the CMP number (pseudo-identifier) on screening logs. Only anonymised data on inclusion/exclusion criteria met will be included on the screening log and submitted to ICNARC, as per advice from CAG Chair team.

Therefore, the NDOO will be respected, and no confidential patient information will be processed for those patients that have applied the National Data Opt Out (NDOO), but anonymised data will be disclosed to ICNARC. This is in line with advice from the CAG chair team regarding the use of anonymised data of those where the NDOO has been applied. The Chair team have agreed that Trusts are able to share effectively anonymised data for an audit for those patients that have registered their NDO, as this is not in scope for 's251' support, provided that

1- they follow the standard of anonymisation as outlined in the ICO code of practice, and

2- they consider that any other data held by the receiver of the data does not lead to any re-identification

The CAG would therefore like assurance from the applicant that the sharing of anonymised data regarding any patient registering an NDOO will be undertaken via the standard of anonymisation as outlined in the ICO code of practice, and that this is undertaken by staff who are considered direct care team to avoid any breach of confidentiality.

The Committee considered the notifications provided, and although understanding the difficulties of notifying this particular cohort, CAG felt that these documents should be improved, as they were currently confusing, and missing information. The Poster/leaflet does not mention CAG or the use of 's251'. The privacy notice very briefly mentions CAG, but not the element requiring 's251' support regarding those screened but not included, and also incorrectly describes CAG 'approval' whereas CAG is permissive and provides advice rather than approval. It is also not clear where the privacy notice is planned to be displayed. Currently, there does not appear to be any opt out options available for patients to opt out of the elements covered by 's251'.

The applicant is to use a layered approach of notification. The poster for the relatives room should be re-designed to be more informative, but also ensure that it signposts people to where they can find more information, in the form of a leaflet (available in the unit), and a website. In this way people can read on further if they wish to. The poster should be clear who the cohort covered by 's251' support are, and describe what the breach of confidentiality is, in order that people can identify if they are likely to be included or not, and therefore enable people to opt out if they wish to. The use of 's251' as a legal basis under common law should be mentioned, and an opt out option should be provided. It should be noted to the applicant that this opt out option is only relevant for the patients themselves, as a relative cannot opt out on behalf of someone unless they are the legal representative.

The leaflet and study website should describe in further detail the data flows supported under ‘s251’, and again provide opt out options. The updated documents should be reviewed by patients and lay individuals to ensure that the language is understandable.

It is understood that there are quarterly extracts of outcome data planned, and continual data collection from Trusts. If a patient opts out at any time point, it should be possible for this to be updated, until 2024, as the applicant will be able to identify individuals up until that timepoint, even it is after they have been included in the dataset.

Patient and Public Involvement and Engagement

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

The Trial Management Group includes one Patient and Public Involvement (PPI) representative (former ICU patient) who has and will provide vital patient engagement and has reviewed all patient materials used in the trial.

The study protocol, particularly the consent and follow-up procedures, has been reviewed and modified by patient and public representatives on the Trial Management Group and independent PPI representative on the Trial Steering Committee. Applicants have further sought the views of ICNARC patient and public representatives (who participated in other adult critical care trials) comprising a total of seven patient and public representatives, about using patient identifiable data without explicit patient consent for the specified situations described in this application. All members were supportive of the processing of minimal identifiable data for participants whom explicit patient consent was unable to be obtained (e.g. because the patient died or was discharged prior to regaining capacity).

In addition to the use of patient identifiable data without consent or consultee opinion, the impact of the National Data Opt Out (NDOO) on the trial was also raised with the patient and public representatives, including the mitigation strategy of collecting pseudonymised information for patients enrolled in the trial with an NDOO and for whom explicit patient consent was unable to be obtained. The majority of the patients were supportive of the collection of minimal, anonymised information about patients with NDOO to prevent bias and ensure validity of the results for future patients. Two patients expressed some reservations about whether collecting minimal anonymised data regarding these patients would be seen to ‘override’ their wishes but agreed that it was important for the trial outcomes and was encouraged that no identifiable data would be transferred outside of the local UK-ROX team.

The committee noted that the applicant has stated there is one patient representative on the Trial Management Group (TMG), and then in another place written that there is

one patient representative on the Trial Steering Committee (TSC). The Members were therefore not clear if this was 2 different representatives, or if the terms TMG and TSC were interchangeable. It was considered that a maximum of eight patients representative of the cohort appeared to have considered this use of confidential patient information without consent. This application is regarding approximately 300 patients for whom consent or consultee advice was not gained, but also for approximately 53,000 individuals who were screened but not enrolled. The CAG therefore felt that further patient and public involvement should be undertaken to establish the acceptability of this use of confidential patient information without consent, to ensure the patient and public involvement was proportionate to the number of individuals included with 's251' support.

Exit strategy

Patient recruitment started in 2021 and will end in 2023. January 2023 is the end of planned patient recruitment, and April 2023 is the planned last follow-up. Within a year of completion of the trial, all identifiable data will be anonymised and confidential patient information collected under 's251' support destroyed. Therefore 's251' support required until April 2024. The applicant will only retain confidential patient information for the consented cohort, and this is out of scope for CAG. 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.

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

Request for further information

1. Please confirm that the global sharing of data collected under 's251' support would only be relevant to the estimated 300 patients included in UK-ROX from whom patient consent, or consultee opinion, was unable to be obtained. Please confirm what data would be shared, and please confirm that the data would be considered effectively anonymous.

2. Please alter the patient notification document sent to those who are discharged prior to consent or consultee advice being gained, to ensure it is not asking for explicit consent, and stating that linkage to outcome data would be undertaken with 's251' as the legal basis under common law, and include details of how the

participant could opt out of this. The letter should also say the patient could call for further information, at which stage the patient could then be consented if they get in touch with the study team. This updated document should be provided to CAG for review.

3. Regarding any patient who is included in the study with ‘s251’ support because they were discharged prior to either consent or consultee advice being gained, please advise if it would be possible for the initial treating clinician to seek consent at any in-hospital follow up?

4. Please clarify if sex is required for analysis rather than gender?

5. Please provide assurance that the sharing of anonymised data regarding any patient registering an NDOO will be undertaken via the standard of anonymisation as outlined in the ICO code of practice, and that this is undertaken by staff who are considered direct care team.

6. The poster, leaflet and website text should be revised in line with advice in this letter. The cohort and the specific breach of confidentiality should be described, along with what data items will be shared, between which organisations for which purposes. The role of CAG should be described, regarding the need for ‘s251’ support, and an opt out option specifically for the data flows covered by ‘s251’ should be offered. The updated patient notification documents should be discussed with patients and the public.

7. Further patient and public involvement should be undertaken to establish the acceptability of this use of confidential patient information without consent.

8. Please provide Favourable opinion from a Research Ethics Committee regarding the amendment that introduced the need for CAG, as per standard condition of support below.

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

Specific conditions of support (provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Pending (regarding amendment that introduced need for CAG. original REC Favourable Opinion given 17 Feb 2021)**

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

   The NHS Digital **21/22** DSPT reviews for **The Intensive Care National Audit & Research Centre (ICNARC) and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 23 November 2022)

   Digital Health and Care Wales (DHCW) has a valid CpiP in place as confirmed by the Welsh Information Governance team.

   Due to the number of participating ICU's involved it is the responsibility of ICNARC, as controller, to ensure that these participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

4. Any other business

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

Signed – Chair	Date
Dr Murat Soncul & Ms Clare Sanderson, CAG Alternate Vice Chairs	*28 November 2022 & 30 November 2022*

Signed – Confidentiality Advice Team	Date
Mr William Lyse, HRA Approvals Administrator	*25 November 2022*