Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

April 2023

1. New Applications

a. 23/CAG/0012 - Utilising data linkage to investigate the health impact of carrier status for common genetic disorders

Name	Capacity
Professor William Bernal	CAG Alternate Vice Chair
Dr Katie Harron	CAG Member
Mr Marc Taylor	CAG Member
Professor Sara Randall	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from Cardiff University set out the purpose of medical research that seeks to explore the effects on health of carrying the Cystic Fibrosis gene.

Cystic fibrosis (CF) is a common life-limiting genetic disease. A person is affected by CF when they inherit two changed copies of the CFTR gene. Individuals with only one changed copy are called 'carriers'. Carriers are usually unaffected by severe disease. However, there is emerging evidence that being a carrier for conditions such as CF may still have health implications that are not well understood. This study aims to examine the health implications for CF carriers in the Welsh population.

The applicants will collect CF genotype data from the All Wales Medical Genomics Service (AWMGS). The CF genotype data will be pseudonymised and submitted to the Secure Anonymised Information Linkage (SAIL) Databank. In SAIL the CF genotype data will be linked to anonymised health data from the Welsh population.

Confidential patient information from the CF genotypes database at All Wales Medical Genomics Service (AWMGS) will be submitted securely to Digital Health and Care Wales (DHCW). The data will be separated into demographic and clinical information. Confidential patient information will be removed from the demographic data and replaced with an Anonymous Linking Field (ALF), allowing linkage to electronic health records within the SAIL Databank. The clinical data will be imported to SAIL directly and recombined in SAIL to give the recombined, anonymised CF-carrier cohort consisting of genotypes linked with data from the electronic health records. Control data will be exclusively sourced from existing data held by SAIL and support for matching controls to the project data will be provided by a SAIL engineer. The researcher will access the linked dataset within the Secure eResearch Platform (SeRP) through SAIL Gateway exclusively. No data will be disclosed to Cardiff University systems at any point.

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	Male and female patients who are: CF-carriers (patients with a genetic test result consistent with a diagnosis of heterozygous for one CF causing mutation on the CFTR gene according to the CF8 or EU2-50 mutation lists) CF-patients (patients with a genetic test consistent with homozygous or compound heterozygous for CF-causing

	mutations in the CFTR gene according to the CF8 or EU2-50 mutation lists Patients who underwent CF-screening and came back negative Control groups (a suitable age- and sex- matched control group with 10 controls per CF carrier derived from the general Welsh population) 4000 is the total UK patient sample size, plus 40,000 controls.
Data sources	1. All Wales Medical Genomics Service (AWMGS), hosted by Cardiff and Vale University Health Board 2. SAIL Databank
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Postcode
Identifiers required for analysis purposes	1. Postcode 2. Gender 3. Ethnicity

Confidentiality Advisory Group advice
A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Patient and public involvement needs to be undertaken specifically around the use of confidential patient information without consent and feedback from this provided to the CAG.**

    a) **Patient notification materials and a dissent mechanism need to be created and discussed during patient and public**

involvement. Draft materials and information about the dissent mechanism need to be provided to the CAG.

b) **Creation and review of patient notification materials aimed at children under the age of 16 needs to be undertaken.**
c) **Patient and public involvement also needs to include representatives from the population that the control group would be drawn from.**

As part of their application to use SAIL data, the applicants will be required to submit the project for review by the Information Governance Review Panel (IGRP) at SAIL which comprises members of the public. Feedback from the IGRP will be provided to CAG.

The applicants also plan to engage with the Genomics Partnership Wales (GPW) sounding board on the matter of confidential patient information without consent as proposed in the application. This consultation is scheduled for the 19th April 2023. Feedback can be provided to the CAG.

As part of the focus group, the applicants explored how ongoing communications could be undertaken. The best format was judged to be a combination of text and video content, both comprising a short lay summary and longer lay explainer.

The materials have been reviewed against guidelines from the Information Commissioner's Office on how the right to be informed applies to children. The video content will be adapted to be applicable to all ages. More comprehensive information will be available in the text document.

The SAIL IGRP panel involves members of the Welsh public whose data in SAIL will contribute to the population our controls will be drawn from. The GPW Sounding Board is similarly composed.

In addition, social media will be used to engage with the public. The benefit of using social media is that it does not differentiate between individuals who will form part of the test or control groups, so any engagement or involvement managed through social media and blogging will be widely targeting.

The CAG was largely satisfied with the patient notification materials, but noted concerns that the material presented in the PowerPoint presentation would be easily understood by 10–14-year-olds. Members asked that feedback on the reception of the presentation is provided at the first annual review.

2. **Clarification on how the results of the study will be disseminated needs to be provided.**

The results of the study at completion will be disseminated through scientific journals and conferences. The applicants will also organise a public talk through the CF Trust to report the general findings of the study and future directions.

Throughout the lifetime of the project, results and updates will be disseminated as described above. Members of the public will be given the chance to offer suggestions of how they would like to see results.

3. **Provide clarification on the postcode level required for analysis. If the full postcode is required for deprivation scoring, please advise why the full postcode is needed, or whether it could be converted to Index of Multiple Deprivation.**

The applicants explained that the full postcode is required for the linkage process. For analysis purposes, postcodes will be converted to Lower Super Output Area (LSOA).

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Feedback on the reception of the presentation given to 10-14-year-olds is to be provided at the first annual review.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 02 March 2023.**

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:**

   SAIL Databank and SeRP (within Swansea University) – DSPT in place for 2021/22

   Cardiff and Vale University Health Board – CPiP in place

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

Name	Capacity
Ms Clare Sanderson	CAG Alternate Vice Chair
Ms Rose Payne	CAG Member
Mr David Evans	CAG Member
Dr Rachel Knowles	CAG Member
Dr Sandra Duggan	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

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

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

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

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

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

Confidential patient information requested

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

Cohort	All men who have ever been admitted to and discharged from the Millfields Unit between 01 January 2005 – 31 December 2021 or the PIPE at HMP Swaleside between 01 January 2014 – 31 December 2021. For the control group, men who were referred to the PIPE, but not admitted, between 01 January 2014 – 31 January 2019 are eligible for inclusion. 150 patients will be included in the control group. Approximately 80 patients will be recruited from Millfields Unit and 100 from Swaleside PIPE.
Data sources	1. Patient records at the Millfields Unit (East London NHS Trust) and HMP Swaleside

Identifiers required for linkage purposes	1. Name 2. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Prison/hospital security level 4. Accommodation type 5. Gender 6. Occupation 7. Ethnicity

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

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

The applicants explained that the study will evaluate the effectiveness of the respective treatment models of each service. The findings will be used to improve care of patients within the offender personality disorder pathway and inform future models of treatment. The CAG noted this and raised no further queries.

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

The applicants confirmed that the records held by HMP Swaleside are not health records. The CAG noted this and raised no further queries.

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

As the data from HMP Swaleside will not be processed under s251 as it is not health information, the National Opt-Out will not be applied to this data. The CAG noted this and raised no further queries.

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

The applicants advised that they had originally created patient notification documents. However, the HRA REC had asked that the materials were not used.

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

Not applicable, please see point 4 above.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed: 22 July 2022.**

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

   The **NHS Digital 2021/22** DSPT review for **East London NHS Foundation Trust** is confirmed.

c. 23/CAG/0021 - CSOR: Children's Surgery Outcome Reporting Research Database

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Dr Sandra Duggan	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Andrew Melville	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from National Perinatal Epidemiology Unit, University of Oxford set out the purpose of creating a research database containing data relating to children treated for necrotising enterocolitis (NEC), Hirschsprung's disease (HD), gastroschisis, posterior urethral valves (PUV), congenital diaphragmatic hernia (CDH) and oesophageal atresia (OA).

The database will be comprised of three linked sources of data about children with specific surgical conditions. The data collected will be used to identify unwarranted variation in practice and for the conduct of approved research to improve outcomes for children with these conditions. A consented and an unconsented cohort will be included in the database. Should local site staff, which may be either the clinical care team and research nurses, come into contact with the parents of a child who is eligible for participation, they will speak to the parents about the CSOR database. Patients may also be flagged to the CSOR Research Database team via a flag placed on the infant's electronic patient record (EPR), highlighting that infant's data for extraction, by the presence of an ICD10 code in the NHS England record of a child who has been admitted to one of the participating sites over the past month, or via parental self-registration through the CSOR parent portal.

Support under s251 is required to allow collection of confidential patient information for eligible children directly from the EPR at participating trusts and HES data from NHS England without consent. Surgeons at participating trusts will flag the records of eligible patients in their trusts EPR. Monthly reports of eligible infants will be generated by hospital Informatics teams at participating trusts and transferred to Oxford University Hospitals NHS Foundation Trust. Confidential patient information will be disclosed from Oxford University Hospitals NHS Foundation Trust to NHS England for linkage to the HES dataset. A monthly extract of confidential patient information for patients meeting the eligibility criteria will also be provided by NHS England. The research data will be linked and pseudonymised by staff at Oxford University Hospitals NHS Foundation Trust and the pseudonymised dataset transferred to the University of Oxford for analysis. Quality of life data will also be collected from parents of a consented subset of these infants and linked to data collected from the other sources

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

Confidential patient information requested

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

Cohort	Children diagnosed with any of the following six conditions: 1.Hirschsprung's disease 2.Oesophageal atresia 3.Gastroschisis 4.Necrotising enterocolitis 5.Posterior urethral valves 6.Congenital diaphragmatic hernia Who were admitted to any of the participating sites.

Data sources	1. Hospital Episode Statistics (HES) dataset, NHS England 2.Infants' Electronic Patient Records, held at participating sites: a. Oxford University Hospitals NHS Foundation Trust b. Southampton Children's Hospital c. Alder Hey Children's Hospital d. Manchester Children's Hospital e. Great Ormond Street Hospital for Children f. Chelsea and Westminster Hospital g. Addenbrookes Hospital, Cambridge h. Birmingham Children's Hospital i. Evelina Children's Hospital, Guy's and St Thomas' NHS Foundation Trust 3. Parent (participant) provided Schedule for the Evaluation of Individual Quality of Life – Direct Weighting (SEIQoL-DW) data
Identifiers required for linkage purposes	1. Name 2. NHS number 3. GP Registration 4. Date of birth 5. Date of death 6. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level 2. Ethnicity

Confidentiality Advisory Group advice
A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Provide further precise information on why patients cannot be consented either during their hospital stay or during clinic visits.**

The applicants provided further details on why the study design had been decided on. The CAG reviewed this information and raised no further queries.

2. **Provide clarification on the impact on the statistical analysis should all patients treated at participating units not be included.**

The applicants provided further details on the impact on the analysis should all patients not be included. The CAG reviewed this information and raised no further queries.

3. **All patient notification materials need to explain how confidential patient information will be used in the study and how patients, or their parents, can dissent from inclusion in the application. The postal address should be added to patient notification materials as a means of seeking a local opt-out.**

A postal address had been added to the site poster.

The applicants confirmed that the website will be updated once the required approvals and support for the database are in place. The site will contain the text from the site poster, links to the Introduction Participant Information Leaflet, the Patient Information Leaflet, Consent Form and Privacy Notice. The text will contain all the basic information required for notification, and the links will contain more information for those who would like to

know more. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed (Favourable Opinion issued 10/11/2022)**

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 NHS Trusts involved, it is the responsibility of NHS England, as controller, to ensure that NHS Trusts 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 about a Trust.

d. 22/CAG/0163 - Real Time Suicide Surveillance System (Wales)

Name	**Capacity**
Mr Tony Kane	CAG member
Mr Andrew Melville	CAG member
Professor Sara Randall	CAG member
Ms Diana Robbins	CAG member
Dr Murat Soncul	CAG alternate vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application submitted by Public Health Wales, sets out the purpose of continuing to develop a Real Time Suicide Surveillance System (RTSSS) for Wales, in order to inform suicide prevention across Wales, and for ongoing monitoring of the impact of the pandemic on suspected suicide deaths. Reports will be provided to partners including the Welsh Government, police lead and public health teams, and an annual surveillance report will be published on the website. The RTSSS can also be used in instances where a public health concern has arisen, or to answer specific ad hoc requests.

The Welsh Government (Mental Health and Vulnerable Groups policy team) commissioned a national repository for (suspected) suicides within the Public Health Data, Knowledge and Research directorate in Public Health Wales, and the RTSSS for Wales was established in Public Health Wales from 1st April 2022, without the use of confidential patient information. However the applicants are applying for 's251' support to undertake the RTSSS because it has become clear that confidential patient information was required to ensure duplicates are not created, to link new information to existing records, and to request further information from other sources.

's251' support is requested to allow identifiable information to be disclosed from Health boards to Public Health Wales about patients who die where the event that led to their death was a suspected suicide attempt. Information from the NCCU will be provided about deaths from suspected suicide of Welsh residents who die in commissioned services outside of Wales. Information from mental health services and other health services about patients who have died by suspected suicide with information on their medical and mental health history, and use of medical, mental health and substance misuse services at the time of death and 12 months prior will be provided. Confidential patient information may be provided from prison services, and from ONS. Data from the police and the media will be provided, but this is not in scope for 's251' support as it is not confidential patient information. HM Coroner will also provide data which is out of scope for 's251', as it is in the public domain. Data will be de-duplicated and linked together. English RTSSS systems are also planned to be data sources for the RTSSS however details are not yet known and will be included as an amendment later.

PHW may request additional data from other data sources. To undertake the 2-way flow, name and DOB will be inputted to Welsh Demographic Service Dataset (WDSD) controlled by DHCW, via secure login to obtain NHS number. NHS number is inputted to Welsh Clinical Portal (WCP) controlled by DHCW, via secure login to obtain clinical information. Name/DOB/NHS number is disclosed to Welsh health board/GP via password protected file via email to obtain further clinical information, or to English Trusts. Name/DOB is disclosed to HMPPS via password protected file via email to

obtain information on sentence length/ probation status. ‘s251’ support is required for this flow, but not the flow back, as that would not constitute patient information. Name/DOB disclosed to HM Coroner via password protected file via email to obtain information on inquest conclusion. ‘s251’ support is required for this flow. No ‘s251’ support is required for the flow back, as the inquest conclusion information flowing back would be publicly available.

PHW require further support for flows relating to data validation, which are not mentioned in the application, only in the data flow diagram, submitted as a result of CAT queries. PHW will disclose date of death, age, health board of residence and health board of location of death to NHS Wales Delivery Unit where individual was known to mental health services in order to validate against Nationally Reported Incident held by the DU. If missing cases held by the DU, further information sought from Police. ‘s251’ support is required for the flow of confidential patient information to the NHS Wales Delivery Unit, and the police, but not for any flow back. PHW will disclose date of death, age and location of death to the British Transport Police in order to validate against BTP data. If missing cases held by the BTP, further information sought from local Police force. ‘s251’ support is required for the flow of confidential patient information to the BTP, and the police, but not for any flow back. PHW RTSSS will disclose name and date of birth Child Death Review Programme, also held by Public Health Wales, to validate against CDRP data. If missing cases held by the CDRP, information is saved in secure file location on PHW network and information is uploaded to the RTSSS database. ‘s251’ support would be required for this disclosure and any corresponding inclusion into RTSSS.

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

Confidential patient information requested

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

Cohort	Suspected suicide deaths of individuals who die in Wales (Welsh residents and non-Welsh residents) & Suspected suicide deaths of Welsh residents who die elsewhere

	It is anticipated that around 300-350 deaths will be reported to RTSSS per year. Electronic data on suspected suicides from 1st April 2022 are stored in the RTSSS database However support is only relevant for data collected after ‘s251’ is in place.

Data sources	Initial disclosure:
	
	• Primary care or health boards in Wales or Trusts in England if death occurred there (including Critical Care Units, Mental Health Services, Substance Misuse Services)
	• National Collaborative Commissioning Unit hosted by Cwm Taf Morgannwg University Local Health Board
	• HM Prison and Probation Service in Wales
	• Office for National Statistics
	
	Follow up information:
	
	• General practitioners · Welsh health boards/English Trusts/ mental health services /substance misuse services
	• Digital Health & Care Wales (DHCW)
	  ○ Welsh Clinical Portal
	  ○ Welsh Demographic Service Dataset
	• HMPPS
	• HM coroner
	
	Data validation:
	
	• NHS Wales Delivery Unit (Nationally Reported Incident data)
	• British Transport Police
	• Public Health Wales (PHW) - Child Death Review Programme
	
	Processors not in scope:
	
	• 4 Welsh Police forces (not in scope for ‘s251’)

	• Senior coroners in Wales or England (not in scope for 's251') • Media
Identifiers required for linkage purposes	1. Forename 2. Surname 3. Date of birth 4. Date of death 5. Address 6. Postcode 7. NHS number
Identifiers required for analysis purposes	No identifiers required for analysis, except occasionally, Full date of death (Only month and year of death for the majority of analyses. However, for any potential suspected suicide cluster investigation, it may be possible that applicants would need to produce a chart showing dates of death, for a very limited audience (i.e. Directors of Public Health and multiagency professional members of a cluster response group).

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Please confirm that this application is for non-research purposes, and that no corresponding research application is required.**

The applicant confirmed this, and the CAG accepted the response.

2. **Please submit an updated data flow diagram, with the common law legal basis for each flow of data clearly labelled so it is clear what 's251' support is requested for.**

The applicant has provided an updated data flow diagram, accepted by the CAG. The applicant stated that no 's251' support is required for the flow back of inquest conclusion information the flow back from the Coroner, as this would be publicly available.

3. **Please clarify what the legal basis under common law is for the Child death review Programme, controlled by public Health Wales.**

The applicant confirmed that the legal basis under common law for the CDRP is 's251' support, and has provided the CAG reference - 19/CAG/0177. The CAG were content with this response.

4. **Please consider minimisation with regards to the two-way data flows, and confirm if the flow can be undertaken with only a pseudonymous ID, or provide justification as to why not.**

With regards to two way data flow, when information is being requested from another organisation, the applicants have confirmed they can request that the flow of information back to PHW uses a pseudonymised ID. 's251' support will still be required for these flows, as PHW will have the means to re-identify, however the CAG were content with this minimisation of flows of identifiable information.

5. **Please confirm if you plan to retain full date of death for all participants in the RTSSS. Please confirm if there is a time point at which full date of death could be deleted.**

The applicant confirmed that they plan to retain full date of death indefinitely for all participants in the RTSSS. This is because the exact date of death may be of relevance for other linked deaths that may occur in the future e.g. anniversaries of family members / a look back exercise about suspected suicides that happen in a geographical space (not necessarily time, as there may be several years between deaths), where the actual date of death may be relevant. This could however be reviewed in future. The CAG were content with this justification.

6. **Please confirm if all identifiable information (aside from date of death) can be deleted from an individuals RTSSS record after de-duplication and linkage. If so, please confirm a timeframe. If not, please provide justification.**

The applicant confirmed that currently, it is not known how long the process of linkage could take. Inquests can take up to several years, so the final piece of information to add to the case record may be a significant length of time after the date of death. In addition to this, if identifiable information is retained, it may be possible to identify linked cases in the future e.g. same surnames at the same location, and identify whether there are any possible clusters (in space) of concern. The CAG were content with this justification.

7. **Please update the website with more detailed information about the data sources and flows which are happening under 's251' support, and the legal basis under common law for the creation of the RTSSS should be explained.**

The applicant provided a draft of the updated website text, and the CAG were content with the wording provided.

8. **The applicant should engage with families managing bereavement, to undertake patient and public involvement to discuss the acceptability of this use of confidential patient information without consent.**

The applicant confirmed that they work closely with the Suicide and Self-harm prevention team based in the NHS Wales Collaborative, who are at the early stages of planning a lived experience network to include those who have themselves had suicidal thoughts/attempts, those who are managing self-harm behaviour and those who have been bereaved by suicide. Their plan is to work alongside the Samaritans and the National Suicide Prevention Alliance to establish a funded lived experience network for Wales. This will take approximately 12 months to establish, and the aim would be for the network to co-produce, support and inform national and regional work. Although this means that it could be more than 12 months until RTSSS would be able to discuss the acceptability of this use of confidential patient information without consent with families managing bereavement, the applicants feel that engaging via this mechanism is the most appropriate route to take, since appropriate safeguards would be in place for bereaved families. Updates on the progress of this work will be provided to CAG. Although the Sub-Committee would have preferred some patient and public involvement to be undertaken prior to 's251' support being

provided, the Members agreed that the plan described was appropriate, and did not wish to hold up the application. The applicant is therefore asked to undertake patient and public involvement as described, and ensure feedback is provided to CAG at the time of the first annual review – 20 April 2024.

9. **Please confirm that staff who access confidential patient data from their homes are accessing data via a VPN (Virtual Private Network).**

The applicant confirmed that staff who have access to confidential patient data from their homes will be able to access only via VPN, and the CAG were content with this response.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. ‘s251’ support will be provided for five years in the first instance. A duration amendment will be required at that time in order to extend support.

2. RTSSS English sources are currently not in scope for ‘s251’ support, and will be included as amendments if required.

3. The applicant should engage with families managing bereavement, to undertake patient and public involvement to discuss the acceptability of this use of confidential patient information without consent, as per the plan provided to CAG, and provide feedback to CAG at the first annual review.

4. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. **Confirmed:**

Public Health Wales is confirmed as meeting the standards required by the Welsh information governance team.

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

e. 23/CAG/0020 - Early behaviour predicting adherence to Continuous Positive Airway Pressure therapy in patients with Obstructive Sleep Apnoea: a growth mixture modelling analysis

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Professor Sara Randall	CAG Member
Mr Dan Roulstone	CAG Member
Mr Marc Taylor	CAG Member
Mr David Evans	CAG Member
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from Imperial College London set out the purpose of medical research that seeks to investigate patterns of Continuous Positive Airway Pressure (CPAP) usage patients with Obstructive Sleep Apnoea (OSA) develop when they first starting using CPAP therapy.

One billion people worldwide and 8 million people in the UK (24.5% of the population) are estimated to have Obstructive Sleep Apnoea (OSA). It is the most common sleep disorder and is characterised by frequent pauses in breathing during sleep due to airway blockage, caused by intermittent relaxation of the throat muscles. Patient's sleep is broken, causing patients to complain of sleepiness, fatigue, difficulty in concentrating, memory impairment and feelings of irritability and depression. Patients' and their bed partner's, quality of life is reduced. Patients are also at a higher risk of developing Type 2 diabetes, high blood pressure, heart disease, strokes, and are more likely to die of all causes, compared to those without OSA. Patients with OSA may receive CPAP therapy, where a device with a facemask is worn whilst sleeping. This device delivers air at positive pressure. Used regularly, CPAP therapy improves quality of life for patients and their bed partners and reduces patient's risk of death. However, within 3 months of starting CPAP therapy, between 48% and 73% of patients are not using CPAP for 4 hours per night for 70% of nights. In the UK in 2020, 58% of patients were not using CPAP 3 months after beginning therapy. Interventions, such as behavioural interventions, have been developed, however these interventions are complex and are not cost-effective or feasible for clinical adoption. The applicants seek to develop an intervention which can be translated into clinical practice.

The applicants have already collected data from remote monitoring of CPAP devices for five centres. The applicants require support to process confidential patient information for patients treated by Wythenshawe Hospital, part of Manchester University NHS Foundation Trust, to collect data for a validation cohort. A consecutive list of 100 patients will be extracted from the Airview database for Wythenshawe Hospital, Manchester University NHS Foundation Trust, from 2019, avoiding patients used for the previous analysis. Each individual patient will be checked for eligibility and patients excluded as necessary. CPAP-usage datafiles will be downloaded for each patient at each of the relevant time points over three months and recorded in the results database under a code number. The relevant clinical data obtained from the electronic patient records system will be recorded in the results database. The process will be continued until data from 100 patients is collected. The process will be repeated for a second patient sample treated in 2021 and therefore treated under a different clinical pathway. This database and the pre-existing database of 1000 patients, both pseudo-anonymised, will be transferred to the statistician.

A recommendation for class 1, 4 and 5 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	Male and female patients aged 18 years and diagnosed with Obstructive Sleep Apnoea (OSA) 1200 patients will be included in total, 100 of which will come under the scope of support.
Data sources	1. Electronic patient records at Wythenshawe Hospital, part of Manchester University NHS Foundation Trust
Identifiers required for linkage purposes	1. Hospital ID number 2. Date of birth
Identifiers required for analysis purposes	1. Gender

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Please clarify the correct number of patients included under the scope of support.**

The applicants advised that data would be collected from 200 patients in total. These will be from 100 patients who started CPAP in 2019 and a further 100 patients who started CPAP in 2021, both who were under the care of Wythenshawe Hospital sleep service. The CAG raised no further queries.

2. **The data already collected from remote monitoring of CPAP devices for five centres is outside the scope of support.**

The applicants noted this confirmation. The CAG raised no further questions.

3. **Advise whether the data can be collected prospectively, so consent could be sought from patients in advance of the data collection, removing the need for s251 support.**

The applicants explained that prospective data collection would potentially introduce bias. The applicants noted that patients who are more reluctant to starting using CPAP would be less likely to consent to enrol in the research if they were aware that their CPAP use would be monitored carefully. This would affect the results of the study as less data on non-adherent patients would be included. The CAG noted this information and raised no further queries.

4. **Patient notification materials need to be created. The materials need to describe the purpose of the study, details of the research team, and how patients can opt-out. The CAG usually expects that telephone, email and postal contact details are provided, should patients have queries or wish to dissent to the inclusion of their data.**

Patient notification materials were provided. These will be displayed on the Imperial

College webpage and in the outpatient sleep clinic at Wythenshawe Hospital, where patients attend for their outpatient appointments and to collect consumables for their CPAP devices, and on Wythenshawe's sleep services webpages, where patients would go for information. The CAG noted this information and raised no further queries.

5. **Clarify whether the patient and public involvement group had discussed the use of confidential patient information without consent. If not, clarify if any further patient and public activity is planned.**

The applicants provided further details on the patient and public involvement carried out. The CAG noted this information and raised no further queries.

6. **Patient and public involvement needs to be undertaken around how patients who did not comply with CPAP treatment can be notified about the research.**

The applicants noted that patients who may not have adhered to CPAP can still be under the Wythenshawe service, attending appointments to try and get help with using the CPAP machine or because they are using alternative treatments. The results of the study would be publicised in the same places the patient notification materials were displayed.

The applicants will also work with two sleep charities, Hope2Sleep and the Sleep Apnoea Trust Association, who disseminate information in their newsletters and conference days, and even if patients are not adherent to CPAP they may still follow those websites.

Focus groups will also be held to explore this issue further.

The CAG noted this information and raised no further queries.

7. **Confirm that the National Data Opt-Out will be applied.**

The National Data Opt-Out will be applied. The patient notification materials have been revised to state this. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 28 February 2023.**

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 **Manchester University NHS Foundation Trust** and **Imperial College London** were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 17 February 2023)

2. New Amendments

22/CAG/0014 - The Trauma Audit & Research Network (TARN)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

Support is in place for clinical teams at Trusts and Health boards (England & Wales) to input data (including identifiers) to the Trauma Audit and Research Network (TARN), at The University of Manchester for the purposes of national clinical audit. Support is also in place for NHS England (previously NHS Digital) and Digital Health and Care Wales (DHCW) to disclose confidential patient information linked to outcome data for all English/Welsh patients with specified trauma ICD 10 codes to TARN, for the purposes of linking to TARN data, and for TARN to disclose this on to individual Trusts, for the purposes of validation.

This amendment sought support to include a further purpose into the current TARN application. TARN have been asked to provide data to a study called ‘*Evaluating ICON: mixed methods study to assess the impact of the ICON programme on coping strategies for carers of crying babies, and rates of abusive head trauma in infants aged under one year.’* This is a medical research study to evaluate the effectiveness of the ICON programme in reducing incidence of abusive head trauma (AHT) in young infants. This application has a separate CAG research application, (reference 22/CAG/0088), which provides the legal basis for the disclosure of confidential patient information from TARN to NHS England (previously NHS Digital). More details on the

linkage process can be found in the CAG outcome letters for 22/CAG/0088. However, to undertake this process, TARN would be sharing identifiable data that had been collected under 's251' for a different purpose to the original TARN application (which covers non research activity only), hence the amendment request.

The TARN patient facing notifications have been altered accordingly.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. This amendment was discussed with the applicant prior to submission, and handling route agreed. Confidential patient information is processed as part of the proposed linkage, which already has a legal basis in place under 22/CAG/0088, and the purposes of the TARN application have been amended accordingly.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **The Trauma Audit & Research Network (J160), University of Manchester** (re data safe haven storage of HES and ONS data), **NHS Digital, Quality Health, and Medical Data Solutions and Services (MSDAS)** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 16 March 2023)

   Department of Health and Care Wales (DHCW) has a Caldicott Principles into Practice (CPiP) Out-turn report with a score of 97.5%, and improvement plan for 20/21 provided 9th June 2021.

   Due to the number of participating care providers involved it is the responsibility of TARN, as controller, to ensure that all organisations disclosing confidential patient information to TARN 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 about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

CAG 5-07(d)/2013 – National Emergency Laparotomy Audit (NELA)

Name	Capacity
Ms Caroline Watchurst	Confidentiality Advisor

Context

Amendment request

The National Emergency Laparotomy Audit (NELA) was set up in 2012 in response to a high incidence of death and wide variation in the provision of care and mortality for patients who receive emergency laparotomy (abdominal surgery) in England and Wales. NELA is delivered under contract to the Healthcare Quality Improvement Partnership (HQIP) by the Royal College of Anaesthetists and the Clinical Effectiveness Unit of the Royal College of Surgeons of England.

This amendment informed CAG of additional clinical data items to be included as part of the NELA dataset. These are listed in the submitted amendment documentation, but do not include any additional confidential patient information, and will not increase the identifiability of any individuals.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment, and noted that this was no more disclosive than the current support.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   Confirmed: The NHS England 21/22 DSPT reviews for **Royal College of Anaesthetists and Royal College of Surgeons of England & UKFAST** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 08 March 2023).

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: VIVALDI-CT

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice-Chair
Ms Caroline Watchurst	Confidentiality Advisor

Context

Amendment request

This application is investigating the feasibility, effectiveness and cost-effectiveness of regularly testing care home staff for COVID-19 to protect residents from severe infection and prevent outbreaks. 's251' support is currently in place for the disclosure of confidential patient information (regarding residents admitted to hospital) from care homes to NHS England, for the purposes of linkage to the NHSE Foundry (COVID-19 datastore) (which will then be pseudonymised and disclosed to UCL). An exit strategy was agreed with CAG regarding applying a new pseudo-ID before data flowed to UCL, in order for the dataset to be effectively anonymous.

The applicant has since fully discussed with NHS England how to put this exit strategy into action, and it appears there is a small additional element that requires 's251' support to do this. Therefore this amendment sought support to allow the Chief Investigator (from UCL, and not part of the direct care team) to have access to the key between the persistent NHS England assigned pseudo-ID and the new pseudo-IDs created specifically for the trial until final export of the effectively anonymous dataset for analysis to UCL. 's251' support is required because the CI would technically be able to re-identify individuals (within the NHS E systems) during the course of the pseudonymisation process. This change still reflects the exit strategy with respect to the timings agreed, and the data flow to UCL, however there is the addition of allowing the CI (who is not part of direct care team) to have access to the key between pseudo-ID and identifiers for a short time period, within NHS E systems, in order to appropriately fulfil the exit strategy as agreed with CAG and disclose an effectively anonymised dataset to UCL DSH for analysis. There is no extension to the exit strategy or to the length of time 's251' support is required.

An updated data flow diagram has also been provided for CAG.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs action. The Alternate Vice-Chair considered as there was no extension to the exit strategy that this was a reasonable amendment request.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS England **21/22** DSPT review for **NHS England** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 28 February 2023)

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.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 11 April 2023**

3. Annual Review Approvals

CAG reference	Application Title
ECC 5-02(FT4)/2009	Study of Heart and Renal Protection (SHARP)
CAG 6-06(a)/2014	Welsh Cancer Intelligence and Surveillance Unit (WCISU), Public Health Wales NHS Trust
19/CAG/0214	Understanding the scale and nature of avoidable harm in prison healthcare
19/CAG/0208	Aetiology, timing and risk factors for tuberculosis-associated deaths in London: a retrospective, case-control study
ECC 6-05 (e)/2012	An ongoing case-control study to evaluate the NHS Breast Screening Programme
14/CAG/1020	NHS Bowel Cancer Screening Programme
19/CAG/0160	Evaluation of the NHS Breast Screening Programme – an individual-based cohort study of mortality
ECC 1-04(b)/2010	Evaluating the age extension of the NHS Breast Screening Programme (AgeX Trial)
17/CAG/0103	West Midlands Regional Children's Tumour Registry

21/CAG/0033	Risk of Aneurysm Rupture Study (ROAR)
ECC 1-03(d)/2012	National Gastrointestinal Cancer Audit Programme (National Bowel Cancer Audit)
22/CAG/0009	Early detection of bladder cancer in Yorkshire: Feasibility assessments for implementing a targeted study in populations with high disease specific mortality risk - YORKSure
CAG 9-08 (e) /2014	The EPIC- Norfolk prospective population study
21/CAG/0026	High intensity treatment at the end of life in children with cancer: retrospective, national, data linkage study
21/CAG/0003	Transforming research with routinely collected linked clinical data using an umbrella ethics and governance approach at Newcastle Hospitals
18/CAG/0063	National Early Inflammatory Arthritis Audit (NEIAA)
19/CAG/0215	Fractional Flow Reserve versus Angiographically Guided Management to Optimise Outcomes in Unstable Coronary Syndromes: a developmental clinical study of management guided by coronary angiography combined with fractional flow reserve (FFR) measurement versus management guided by coronary angiography alone (standard care) in patients with non-ST elevation MI
CAG 1-03(PR3)/2014	Next Steps previously known as Longitudinal Study of Young People in England (LSYPE)
21/CAG/0042	The Wynn Database - Metabolic Risk Factors and Mortality
17/CAG/0023	National Bariatric Surgery Registry (NBSR)
20/CAG/0067	Learning Disabilities Mortality Review (LeDeR)
CAG 6-06(c)/2014	Wales Abdominal Aortic Aneurysm Screening Programme (WAAASP) Evaluation
PIAG 2-05(g)/2008	Bowel Screening Wales
ECC 1-06 (c) /2011	National Gastrointestinal Cancer Audit Programme (National Oesophago-Gastric Cancer Audit)

22/CAG/0071	CHARMER WP3 Feasibility Trial
CAG 9-08(c)/2014	MesobanK Retrospective Sample Collection
PIAG 1-05(e)/2006	Frequency of follow-up for patients with low-, intermediate- and high-risk colorectal adenomas
17/CAG/0204	CRIS Linkage with the Office for National Statistics Census Data
16/CAG/0134	Follow-up of the Hertfordshire Cohort Study through Hospital Episode Statistics
PIAG 4-05(e)/2008	NHS Blood and Transplant (NHSBT) – Retrospective Potential Donor Audit (PDA)
15/CAG/0120	National investigation into suicide in children and young people
22/CAG/0051	Our Future Health
15/CAG/0115	UKCTOCS UK Collaborative Trial of Ovarian Cancer Screening
CAG 2-03(PR4)/2014	1970 British Cohort Study
18/CAG/0131	Inflammatory Bowel Disease Registry
16/CAG/0050	ECG Diabetic Foot Ulcer (DFU) Pilot
18/CAG/0038	Yorkshire Lung Screening Trial

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Dr Murat Soncul, Professor William Bernal, & Ms Clare Sanderson, CAG Alternate Vice-Chairs	*10 May 2023*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*02 May 2023*