Health Research Authority

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

August 2022

1. New Applications

a. 22/CAG/0073 - Kidney disease and mental health: Bridging the gap

Name	
Ms Sophie Brannan	CAG member
Professor Lorna Fraser	CAG member
Dr Rachel Knowles	CAG member
Dr Pauline Lyseight-Jones	CAG member
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Ms Diana Robbins	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Michael Pate	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from King's College Hospital NHS Foundation trust set out the purpose of medical research which aims to create a research database to address current gaps in the understanding of the link between kidney disease and mental health difficulties. The applicants hope specifically to determine the prevalence of mental health difficulties in this kidney disease population, and whether there are differences in health outcomes and access to healthcare between kidney patients with and without mental health difficulties. The dataset will also allow researchers to assess future research questions, for example symptom clustering in individuals with Chronic kidney disease (CKD) and significant mental health difficulties, medication usage of individuals with co-occurring CKD and mental health difficulties, and associations between laboratory parameters and mental health difficulties.

Research has demonstrated that chronic kidney disease is more common among patients with mental health difficulties. Life-saving treatments are demanding, and impact the everyday lives of kidney disease patients, often negatively affecting their emotional and psychological wellbeing. It has also been reported that individuals who have been hospitalised for a mental health difficulty have higher mortality rates, and that individuals with a diagnosis of schizophrenia are less likely to receive a kidney transplant. Little is known about how individuals with significant mental health difficulties access kidney care. This application aims to address knowledge gaps, in order to provide more effective long-term solutions and inform the management and support provided to kidney patients with severe mental health difficulties.

This application sought ‘s251’ support to disclose identifiers from the Renalware database from King’s College Hospital NHS Foundation Trust (KCH) to the Clinical data Linkage Service (CDLS) in order for the CDLS to link to mental health data from the South London and Maudsley NHS Foundation Trust (SLaM) Clinical Record Interactive

Search (CRIS) system. Renalware is a database set up in 1998, of kidney patients receiving care at KCH. These datasets will be linked using NHS number, first name, last name, date of birth, sex, and Renalware ID. For matched records, i.e. CRIS-Renalware cases, the CRIS pseudonym (the BRCID) is added to the Renalware data. Controls are defined as Renalware patients who do not match to CRIS. Confidential patient information will then be removed from the dataset for analysis, but the BRCID and Renalware ID will remain. However 's251' support not required for retention of this dataset, as applicant states it is not possible for CDLS staff to re-identify a patient using BRCID. The resulting linked dataset will be stored by the SLaM CDLS for future secondary analysis.

Data will be released to researchers in anonymised format, and will be carried out within the trusted research environment at SLaM. All applications to use the linked data will be reviewed and approved by the CRIS Oversight Committee (OC). The OC is chaired by a service user and has representation from Child and Adolescent Mental Health Services, the SLaM Caldicott Committee (to which it reports), and the R&D Office. There is one lay representative on the OC, applicants are currently recruiting for a second. OC terms of reference have been provided.

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

Confidential patient information requested

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

Cohort	Individuals with kidney disease, from the Renalware database - kidney patients receiving care at King's College Hospital, since 1996 Approximately 7000

	Applicant has stated that patients included in CRIS who do not have kidney disease will also be included. Unclear how many, as they do not yet know prior to undertaking the linkage.
Data sources	1. Kings College Hospital – Renalware clinical database 2. SLaM CRIS database (Mental healthcare data will be provided from the SLAM BRC Case Register)
Identifiers required for linkage purposes	1. NHS number 2. Name 3. Date of birth, 4. Sex 5. Renalware pseudonym ID
Identifiers required for analysis purposes	1. CRIS pseudonym (the BRCID) – no key retained 2. Renalware pseudonym ID – no key retained 3. Year of birth 4. Year of death 5. Gender 6. Occupation 7. Ethnicity 8. sector level postcode Applicant states only de-identified data will be held in the database.
Additional information	Only de-identified data will be accessed by the research team. Analysis of project specific extracts of the data will be carried out within the trusted research environment at SLAM, by applicants who hold a contract with SLaM (either substantive or honorary), indicating appropriate governance and oversight. All applications to use the linked data will be reviewed and approved by the CRIS Oversight Committee.

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 ensure that both KCH and CRIS website notifications will be displayed in good time prior to the data extraction/linkage, to allow people time to opt out. Please clarify to CAG the timeframe prior to linkage that these will be displayed.**

The applicant responded that the website notifications will be displayed for at least 4 weeks prior to linkage to enable people to opt out. The Members were content with this.

2. **Please provide a notification poster for KCH clinical areas, which includes an opt out option.**

The applicant has provided a notification poster which has been reviewed by the King's Kidney Patient Association (KKPA). The CAG were content with this poster.

3. **Please provide updated website text for both KCH and CRIS which is revised in line with the advice in this letter. These should be written in plainer language, with less acronyms. Clarity should be provided regarding the cohort, tenses should be corrected, and a phone number and a postal address (if possible) should be provided for opt out.**

The applicant has provided updated website text as per CAG requests, which has been reviewed by the KKPA and SLAM PPI groups. The CAG were content with the updated website text.

4. **Please undertake some patient and public involvement in a group of patients with kidney disease, but without mental health difficulties, to ensure the acceptability of the use of confidential patient information without consent.**

The applicant has undertaken further PPI with patients with kidney disease from the King's Kidney Patient Association. The patients were very supportive of the application. The Members noted the feedback provided from the meeting in May and are now content to recommend support, but note that they expect the PPI events to continue and expand. This is so applicants can be assured that patients are aware of and

content with this use of their confidential patient information, and are able to continue to contribute to the development of this work

5. **Please provide feedback as to how King's Health Partners Mind Body Programme PPI group have been involved, and please provide information on the plans to work with Kidney Research UK, and Kidney Care UK.**

The applicant stated that King's Health Partners Mind Body Programme team initially reviewed the proposal and were strongly supportive. Applicants have subsequently established a group of service users with lived experience, including with kidney disease who will contribute to development of research questions, data interpretation and dissemination. The CAG were content with this response.

6. **Provide Favourable Opinion from the REC, as per standard condition of support below.**

This was provided 29th June 2022.

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 29th June 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 **20/21** DSPT reviews for **King's College Hospital NHS Foundation Trust and South London & Maudsley NHS Foundation Trust** (CDLS) were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 13 May 2022)

b. 22/CAG/0076 - Suicide by patients in contact with drug and alcohol services in the year prior to death

Name	
Professor William Bernal	CAG alternative vice-chair
Ms Sophie Brannan	CAG member
Professor Lorna Fraser	CAG member
Dr Rachel Knowles	CAG member
Dr Pauline Lyseight-Jones	CAG member
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Ms Diana Robbins	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the Centre for Mental Health and Safety at the University of Manchester set out the purpose of medical research which aims to identify the characteristics and antecedents of suicide in people in contact with substance misuse services. Alcohol and drug misuse are key risk factors for suicide. There is currently no national study of suicide by people in contact with alcohol and drug services, and following NHS reforms, service provision has become more complex. The findings will help to inform preventative efforts in this population.

The applicants plan a 12 month linkage, case-control, and serious incident reports (SUI) collection for England and Wales using National Drug Treatment Monitoring System (NDTMS) and Welsh National Database for Substance (WNDSM). However as the Drug and Alcohol Information System (DAIsy), the Scottish database, is in its infancy, applicants plan only a 6 month linkage with Scottish data, and do not plan to create a control group or collect SUIs regarding Scottish data. This application is in 2 phases. Phase one is a retrospective cohort and case-control study. NCISH at the University of Manchester has 's251' support under **PIAG-4-08(d)/2003** to maintain the general population suicide database. NCISH will extract a sample of people whose deaths have been registered as suicide (including probable suicide) at coroner's inquest. The sample will contain unique NCISH ID number, last name, initial of first name, gender, date of birth, date of death, and NHS number. This will be disclosed from University of Manchester to the Office for Health Improvement and Disparities (OHID), part of the Department of health and Social Care (DHSC), and Digital health and Care Wales (DHCW) (previously NWIS), in order for them to link to NDTMS and WNDSM - databases on all people in contact with drugs and alcohol services from England and Wales. There is also a flow of data to Public Health Scotland (PHS) for the purposes of linkage with the Drug and Alcohol Information System (DAIsy). OHID and DHCW return a linked pseudonymised dataset containing NCISH number back to University of Manchester. This flow still requires 's251' support as the University of Manchester retain identifiers and are able to re-identify these individuals. NCISH will link these data to another dataset retained by University of Manchester, using the NCISH number- the database of suicide deaths in people in recent (i.e. 12 month) contact with mental health services. OHID, DHCW and PHS will securely delete any unlinked mortality data.

OHID and DHCW will create a control sample (using age & sex). Controls will be people who have had contact with alcohol and drug services and have not died by suicide or other causes within 12 months of the matched cases date of death. This data will also have an allocated NCISH number and all identifying information will be removed prior to disclosing to University of Manchester. The applicant has stated these elements do not require 's251' support and that the legal basis for this processing is consent.

In phase 2, applicants will collect detailed clinical data about people who died by suicide while under the care of alcohol and drug services, from SUIs where available. These Incident reports will be obtained by requesting redacted copies from third sector and NHS services organisations providing publicly funded drug and alcohol services. 's251' support is required for the disclosure of name, date of birth, and date of death from University of Manchester to alcohol and drug service providers, in order to request a redacted copy if the SUI. Pseudonymous SUIs are provided back to the University of Manchester, including the NCISH number. Therefore this flow still requires 's251' support as the University of Manchester retain identifiers and are able to re-identify these individuals.

There is no notification or opt out for the case cohort as these individuals are deceased. The applicant has developed a study notification document to be placed on the NDTMS website to inform service users in the control cohort that the study is ongoing. This will link to the longer study notification document on the NCISH website should people wish to obtain more information. This does not have an opt out option as the applicants state that the control group are included with consent.

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	**Phase 1:** Cases: People who have been in contact with drug and alcohol services in the year prior to suicide – Death registered as suicide or probable suicide, between 1st October 2021 to 30th September 2022 (estimated at 545) **Phase 2:** People who have been in contact with drug and alcohol services in the year prior to suicide Death registered as suicide or probable suicide between 1st October 2021 and 30th September 2022, with a SUI report available. (estimated at 545 maximum, however, applicants will try to obtain Serious Incident Reports for all cases, but there will be some that have not had them and some that cannot be obtained)
Data sources	**Phase 1:**

	1. University of Manchester – NCISH databases; a) The general population suicide database (**PIAG-4-08(d)/2003)** b) The database of suicide deaths in people in recent (i.e. 12 month) contact with mental health services. (**PIAG-4-08(d)/2003)** databases on people in contact with alcohol and drug services: 2. Office for Health Improvement and Disparities (England) (OHID), (part of Department of health and Social Care) - National Drug Treatment Monitoring System (NDTMS) 3. Department for Health and Care Wales (previously NWIS) - Welsh National Database for Substance Misuse (WNDSM) Out of scope for 's251' support: • Public Health Scotland (PHS) - the Drug and Alcohol Information System (DAIsy). **Phase 2:** 4. Third sector and NHS services organisations providing publicly funded drug and alcohol services, across England and Wales - serious incident reports (SUI)
Identifiers required for linkage purposes	**Phase 1: For OHID, DHCW, PHS** – from CAG form: 1. Name 2. Date of birth 3. Date of death 4. NHS number (DHCW only) 5. unique NCISH ID number **Phse 2: For SUI:** 1. Name

	2. Date of birth 3. Date of death
Identifiers required for analysis purposes	1. Gender 2. Ethnicity 3. Age Applicant states analysis will be undertaken on an effectively anonymous dataset
Additional information	Key: The data will be pseudonymised within Office for Health Improvement and Disparities (OHID) (England), NHS Wales Informatics Service (NWIS) and Public Health Scotland (PHS). The key between the NCISH identifier and CPI will be held on a secure partition of named networks (OHID, NWIS, and PHS) with limited access to named OHID, NWIS, and PHS staff. Once NCISH are in receipt of the final dataset, the keys will be permanently deleted NCISH will retain a link between the NCISH ID and CPI until November 2023, as they need to retain the ability to remove an individual from the study dataset, if it is subsequently confirmed by ONS/NRS as not fulfilling the NCISH criteria of suicide or open verdict. ‘s251’ support therefore required until that date.

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.

Number	Action Required	Response from the applicant
1.	The applicant should provide an updated data flow diagram. This should provide a clear explanation of the data flows for each country, including which data items are	The applicant provided an updated flow diagram, and CAG accepted this response.

	disclosed, and provide the same regarding the data flows regarding SUIs. The CAG commented that as part of the current data flow diagram, there are comments stating that some flows are; 'Identifiable: Sensitive (not patient information)'. The CAG did not agree with this definition, and considered these flows to be confidential patient information, hence the application to CAG. The updated data flow diagram should clearly define the legal basis under common law relied upon for each flow of data, and should also define the legal bases under common law relied upon for each dataset, for example, the Welsh National Database for Substance Misuse (WNDSM), and National Drug Treatment Monitoring System (NDTMS).	
2.	The applicant is requested to develop a study specific opt out option via NDTMS for the control group.	The applicant responded that this would not be practicable to implement, and that OHID & NCISH are content that the consent to NDTMS is valid for the purpose of creating the control group. The applicants and OHID are therefore of the opinion that a study specific opt out for the control group is not required. The CAG were of the opinion that it should be fairly simple to be able to offer an opt out option, but were content that the PPI was supportive of the application being in the public interest, and therefore accepted that he applicant would not offer an opt out option for the controls.
3.	Please confirm if the patient notification will be displayed additionally on the NDTMS website, and consider developing a poster for display onsite at drug and alcohol service providers. Provide this poster for CAG review.	The applicant confirmed that a shorter patient notification will be displayed on the OHID website regarding NDTMS, and linked to a longer version on the NCISH website.

		Regarding the development of a poster, the applicant confirmed that they were concerned that the creation of a poster would be putting an extra burden onto alcohol and drug services to ask for this to be printed and displayed. The CAG accepted this response.
4.	An updated patient notification leaflet should be provided, which should be much less complicated, and written in plainer language. Members also commented that part of it states 'what rights do we have', and it was noted that the word 'rights' should be altered to 'permissions'. There are incorrect references to NWIS in the notification, and this should be changed to DHCW – the correct organisation. An opt out should be provided as part of this notification. The applicant should consider a layered approach, with a shorter notification stating who the cohort is, the purpose of the study, and how to opt out, and a link to a longer, more detailed statement, should people wish to read on. Additionally it was felt that Patient and Public Involvement opinion should be sought regarding the content of the notification, to ensure it is suitable for a lay audience.	Initial provisions of the updated notification had not encompassed all of CAGs requests. An updated short and long patient notification has now been provided, which has been updated as per CAGs instructions. The applicant has also discussed the notification with a member of the Lived Experience Panel, who provided comments to ensure they were suitable for a lay audience. The CAG were content the response was now sufficient.
5.	Further Patient and Public Involvement needs to be undertaken, with a reasonable number of individuals who are representative of the cohort, surrounding the use of confidential patient information without consent.	**A**pplicants attended a meeting on 28th July 2022, and discussed the application with 6 members of the CGL NLEG regarding the use of confidential patient information without consent. The applicant has provided comments; participants agreed that informed consent is given by individuals for their data to be held on the NDTMS database

		and used for research that is within the best interest of the public. They confirmed that it is clear that an individual can withhold consent and that people do not have to allow their data to be submitted to NDTMS should they not wish to do so. They were all happy for their information to be used for research purposes without obtaining additional consent with the provision that it all checks and balances are made by OHID and all sensible precautions are undertaken by the research team. That data remains anonymous, data is used for the intended purpose (GDPR guidelines followed), and that data is securely destroyed upon completion of the study. Applicants also discussed research which collects data on patients who have died by suicide. Members of the patient and public involvement group felt that in the absence of obtaining consent from the person, it would not be appropriate to seek consent from an individual's relatives due to additional distress to individuals or potential conflict an individual may have had with relatives. The CAG note that it is anyway not possible to obtain consent from the relatives of the deceased under common law, as this is not an appropriate legal basis under common law unless the relative in question is the Legal Personal Representative or the person administering the estate.

		The CAG were content that appropriate PPI had been undertaken.
6.	Further linkages - the applicant is requested to clarify if linkages to further datasets (not currently listed in the application) also represent part of the requested support, as potential linkages with those in touch with mental health service was discussed in the meeting.	Applicants confirmed that no further linkages are to be undertaken than those already listed on the flow chart. The CAG were content with this response.
7.	Exit strategy - The applicant is requested to clarify at which time point the NCISH ID, full date of birth, and full date of death will be deleted from the dataset for analysis, as was confirmed in the meeting, and thereby clarify the timepoint representing the exit strategy from 's251' support.	Applicants will retain only the year of birth and year and month of death once data linkage is complete. NCISH will retain a link between the NCISH ID and Confidential patient information until November 2023, as they need to retain the ability to remove an individual from the study dataset, if it is subsequently confirmed by ONS/NRS as not fulfilling the NCISH criteria of suicide or open verdict. 's251' support is therefore required until that date. The CAG were now content that there was a clear exit strategy from support.

Confidentiality Advisory Group advice conclusion

The further information has been considered by the CAG, who 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 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 24 May 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 **20/21** DSPT reviews **for University of Manchester NCISH - 8D594-ECC0020, DHSC (OHID)** (currently using PHE (X25), will be replaced by UKHSA when this is in place) were confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 13 May 2022)

   - DHCW – a valid CPiP in currently in place.
   - Third sector and NHS services organisations providing publicly funded drug and alcohol services – more than 5, and therefore this is the responsibility of the applicant to ensure.

c. 22/CAG/0092 - Establishing evidence to inform culturally competent mental health services (EVOLVE)

Name	
Dr Patrick Coyle	CAG vice-chair
Mr David Evans	CAG member
Mr Tony Kane	CAG member
Dr Pauline Lyseight-Jones	CAG member
Mr Andrew Melville	CAG member
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Mr Umar Sabat	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Newcastle Upon Tyne sets out the purpose of medical research that seeks to identify and quantify changes to mental health services, and their impacts on health outcomes during the COVID-19 pandemic, in ethnic minorities. Applicants plan to use data collected routinely by the NHS, before, during, and after a lockdown in areas where a large proportion of ethnic minorities live, to compare changes in service use and how changes affect people.

Research has shown that a COVID-19 diagnosis has negative effects on mental health - 1 in 5 people with COVID-19 have experienced a mental health difficulty within 90 days of diagnosis. The pandemic has also worsened longstanding mental health inequalities for ethnic minorities. Research has reported higher levels of anxiety and depression in ethnic minorities across the pandemic, but less support from mental health services. This indicates a need to understand how changes in using mental health services impact health outcomes of ethnic minorities, to establish how services should be provided to satisfy people's needs, which is what this study aims to investigate.

Three local authority areas (Newcastle upon Tyne, Middlesbrough, and Stockton-on-Tees) were selected, as they have a high percentage of ethnic minority individuals living in the region, according to the England and Wales 2011 Census. 6 GP surgeries were then selected. North of England Commissioning Support Unit (NECS) will identify eligible patients and will extract their primary care data, including identifiable information. NECS will then send identifiable information to NHS Digital to link with secondary and community care outcome data. NECS will link the primary care data from the GP practices with the secondary and community care data from NHS Digital, pseudonymise the linked dataset, and provide the linked pseudonymised data to the University of Newcastle. Only NECS will have access to the key between the pseudo ID and confidential patient informaiton, and this will be retained for 35 months after the study has completed, to allow for any requests to check data analysis following publication. The applicants at University of Newcastle will never have access to any identifiable information.

A recommendation for class 4 & 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	1,328 non white patients, from six GP practices across three local authority areas (Newcastle upon Tyne, Middlesbrough and Stockton-on-Tees), who are adults over 18 years having been referred or self-referred to NHS-funded secondary mental health services or Improving Access to Psychological Therapies (IAPT) services between 23 March 2019 and 22 March 2020.
Data sources	1. local primary care electronic health record from 6 GP practices: a. Elswick Family Practice b. West Road Medical Centre c. Elm Tree Surgery d. Riverside Medical Practice e. Park Surgery f. Prospect Surgery 2. NHS Digital: a. Mental Health Services Data Set (MHSDS) b. Improving Access to Psychological Therapies data set (IAPT) c. Hospital Episode Statistics (HES), including; i. Admitted Patient Care (APC), ii. Outpatients (OP), iii. Accident and Emergency (A&E) d. and Community Service Data Set (CSDS)
Identifiers required for linkage purposes	1. NHS number 2. Name 3. Date of birth

Identifiers required for analysis purposes	Pseudonymised data sent to Newcastle University; 1. Date of birth – modified to month and year 2. Date of death – modified to month and year 3. Gender 4. Occupation 5. Ethnicity
Additional information	One off linkage request

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 your understanding that individuals who have not registered a National Data Opt Out have not effectively consented to the use of their data in research.**

The applicant confirmed this was understood, and the CAG were content with this response.

2. **Please re-articulate the justification that consent is not a practicable alternative, by expanding on the bias argument.**

The applicant reasoned that requesting consent would lead to a biased sample because the response rate would be expected to be extremely low in people experiencing mental health problems, who would benefit the most from this study. Therefore requesting consent could mean that the study would not be able to recruit participants who represent the characteristics of the group of people studied. The CAG accepted this reasoning.

3. **Please re-draft the patient notification and poster, as per the advice in this letter. The new documents should be in plainer language, avoiding acronyms, clarify language so as not referring to ethnic minority individuals as having mental illness because of their ethnicity, and make the documents easier to understand by placing the purpose of the study higher up in the order. All references to consent and withdrawal of consent should be removed, and the terminology surrounding opting out should be included instead. These should be translated into other languages. These should be reviewed with patient and public involvement input.**

The patient notification and poster have been revised as suggested, which have further been proof read by the applicants PPI partners. The PPI partners preferred the word "anonymised" to removal of personal information during data analysis. A version of these documents in other languages will be made available on request. The CAG were broadly content with the patient notification documents and were now content to recommend support. However the Members commented that there were still improvements which could be made surrounding clarity, which are made below as suggestions only.

Regarding the section in the privacy notice – '*What if I change my mind and want to opt out of the study? You are free to opt out of the study at any time without having to give a reason, but it would not be possible to remove data from analyses that have already been done. If you feel it is difficult to understand the implications of continuing in the study, we can discuss this with the consultee. Consultees have equal right to opt out of the study if they feel it is no longer suitable for the research to continue. They are able to request that your data are destroyed by the study team, but it would not be possible to remove data from analyses that have already been done. To opt out your data to be used from this study please contact the Data Protection Officer (see email address below).'*

The Members noted that there is a confusion between "you" "the consultee" - is that "you"? and everything changes to "they". It is advised to make this clearer with regards to who is referred to. The Members would also prefer a grammatically correct and easier to understand final sentence, for example; "to opt out from this study....." or "to request that your data are not used for this study...."

4. **Please confirm where the misunderstanding surrounding the National Data Opt Out not being implemented being effectively consenting came from – was this brought up by the patients and public involvement groups, or did the applicants put this idea to the groups? If the applicant put this idea to the individuals, then further patient and public involvement is required, with accurate information provided, to ensure that the use of confidential patient informaiton without consent is acceptable to patient and public representatives of the relevant cohort.**

The applicant confirms that this was a misunderstanding by both the PI and the public members. Further communication and clarification has been made with the engaged VCSE organisations to confirm that we will not equate the lack of use of National Data Opt Out to effectively consenting. On re-explaining the study, the use of routine data without consent was considered to be appropriate because more patients' identifiable information would be required otherwise in order to seek consent. More importantly, it was felt that requesting consent would lead to a biased sample because the response rate would be extremely low in people experiencing mental health problems who would benefit the most from this study. In addition, given the expected low response rate, seeking consent from eligible patients would not meet the sample size required by this study. 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 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 20 June 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 **21/22** DSPT review for **NHS North of England Commissioning Support Unit** (0AR) was confirmed as '**Standards Met'** by email to the CAG inbox (06 July 2022) & the NHS Digital **20/21** DSPT review for **NHS Digital** was confirmed as 'Standards Met' by check of the NHS Digital DSPT tracker (checked 06 July 2022)

d. 22/CAG/0102 - Exploring use and implementation of rehabilitation prescriptions for individuals admitted to UK major trauma centres: a mixed-methods study

Name	
Dr Martin Andrew	CAG member
Mr David Evans	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University of Nottingham set out the purpose of medical research that seeks to explore the current use and intended purpose of the 'Rehabilitation Prescription' (RP) following major trauma, including the context for its implementation. Findings will inform the development of a future grant application, in which a solution to improve the implementation of the rehabilitation prescription will be developed and tested.

Traumatic injuries can be life changing with many survivors experiencing a range of physical and psychological problems. More people are surviving traumatic injury following the opening of UK Major Trauma Centres in 2012, however more individuals are living with the long-term effects of trauma, often requiring rehabilitation. The RP was developed in 2010, designed to support the identification of patient rehabilitation needs. The trauma survivor and family should be involved in its completion with the aim to improve continuity of community care following hospital discharge. However, research suggests that the RP is not being used properly. Patients often feel as if they have been abandoned when they leave hospital with limited knowledge about their rehabilitation plans. The RP is not always being completed by rehabilitation experts and is not always shared with relevant healthcare professionals (e.g. GPs).

The applicant is undertaking a number of different methodologies at 3 participating trauma centres, including consented interviews and focus groups. These elements do

not require ‘s251’ support. However the applicant is also undertaking ethnographic observations, of 3 major trauma centre meetings, observed twice at each site, and observations of clinical staff completing rehabilitation prescriptions. Support under Regulation 5 is required for this aspect of the study as the applicants may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded. Any identifiable data that is recorded (including names of clinical staff and services) will be pseudonymised.

A recommendation for class 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	The participants in the study are NHS staff participating in MDT meetings, and completing the rehabilitation prescription in three trauma centres. However the researchers undertaking observations of MDT meetings may be exposed to confidential patient information relating to patients discussed at the MDT meetings. These will be patients admitted to one of the three major trauma centres (Nottingham, Cambridge, St. George’s London), and will have received a rehabilitation prescription.
Data sources	1. Clinical meetings in major trauma centres recorded via written field notes, at the following Trusts; • Nottingham University Hospitals NHS Trust

	• Cambridge University Hospitals NHS Foundation Trust • St. George's University Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information will be recorded for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be recorded for analysis purposes

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 provide Favourable Opinion from the REC when it is available, as per standard condition of support below.**

The applicant provided the outcome to CAG on 15th August 2022.

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. Please update the poster to make it clearer how to opt out (taking into account the proposed opt out mechanism), and to make it clear that patient data is not collected, and provide the updated poster to CAG within 1 month of the date of this letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 11 August 2022**

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 for **Nottingham University Hospitals NHS Trust**, **Cambridge University Hospitals NHS Foundation Trust**, and **St. George's University Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' by email to the CAG inbox (received 26 July 2022)

e. 22/CAG/0094 - Research to Improve the Detection and Treatment of Latent Tuberculosis Infection: Diagnostics. (Short title: RID-TB:Dx)

Name	
Dr Tony Calland MBE	CAG Chair
Professor Lorna Fraser	CAG member
Mr Umar Sabat	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University College London sets out the purpose of medical research that seeks to conduct an RCT to identify if new C-Tb skin test for the diagnosis and subsequent management of Latent Tuberculosis Infection (LTBI) will be as good as the current standard-of-care IGRA blood test. This will be evaluated based on the number of participants who then accept and start treatment for LTBI, based on a positive C-Tb test result (intervention arm) or IGRA test result (control arm). 's251' support for this application is requested only for the screening and invitation of eligible

patients to a clinic appointment, by individuals who are not considered part of the direct care team.

Latent TB infection (LTBI) testing and treatment reduces TB incidence by preventing reactivation, and is expected to be cost-saving to the health system. However, high rates of testing, treatment uptake and treatment completion are essential to achieve these benefits. There is now a new skin test available, called C-Tb, which research suggests is as good as IGRA in correctly identifying LTBI. Applicants propose to compare the C-Tb test to usual care using IGRA to see whether it is more accurate, easier to obtain a diagnosis, and offers better value for money for the NHS. This study will provide the evidence required to inform the use of C-Tb in UK LTBI testing strategies.

RID-TB is a 5-year programme of research awarded to UCL by the National Institute of Health Research including different studies on latent tuberculosis infection (LTBI). There are various work packages, but 's251' support is only requested for a diagnostic trial (RID-TB:Dx), and that 's251' support is only related to screening and invitation to consent. This RCT has been open to recruitment since September 2021, using the direct care team only to approach eligible patients. And to date, 27 participants have been recruited, out of the required 1530 total. Feedback from existing and potential sites about increasing recruitment rates make it clear that additional support for research staff to contact patients to invite them into clinic and approach them about the study is required.

Recruitment will take place in participating primary and secondary care organisations. 's251' support is required for CRN research nurses/clinical research practitioners, employed through a designated health trust and assigned to the RID-TB programme at UCL and research nurses employed directly by the RID-TB programme, who are not considered part of the direct care team, to view clinical lists, and patient medical records, in order to screen for eligibility, and contact patients via telephone, in order to book them into an appointment for LTBI testing, and consenting to the trial. During the conversation the patients will be asked if they are interested in taking part in TB research. If they decline, they will be booked in to attend clinic for a standard of care LTBI test. If they are interested in learning more about the research, the research nurse/practitioner can provide a brief overview whist on the phone, and then book them in for LTBI testing in the research clinic session. Patient records will be viewed either in person on site or by accessing the electronic patient system remotely. No confidential data will be downloaded/transferred to be stored within a different organisation. The

research nurses/practitioners will also attend the clinics, to present the study before the patient receives their LTBI diagnostic test.

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

Confidential patient information requested

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

Cohort	Participant Inclusion Criteria; 1. Age 16-65 years 2. Eligible for LTBI testing with IGRA and treatment for LTBI according to UK guidance 3. Willing and able to provide written informed consent 4. Willing and able to comply with the trial, including the randomised test(s) and adherence to follow up visits Participant Exclusion Criteria: Displaying any symptoms or signs of active TB disease: Unexplained fever; Cough (more than three weeks); Haemoptysis (Blood in sputum); Unexplained weight loss; Drenching night sweats; Lymph node swelling A total of 1530 participants are to be recruited. 27 have been recruited already. However ‘s251’ support is required for all those who will have their confidential patient information screened. The

	cohort that will be screened are all individuals recommended for LTBI testing and treatment (by UKHSA and NHS England guidelines). This includes new entrants into the UK, and also contacts of TB cases. These will mostly, but not exclusively, comprise of case contacts of persons diagnosed with active TB and persons screened within the migrant screening programme. The LTBI migrant screening programme is for new entrants into the UK (individuals should be tested for LTBI if they are aged 16 to 35 years, entered the UK from a high incidence country (≥150/100,000 or Sub Saharan Africa) within the last five years and been previously living in that high incidence country for six months or longer). It is not possible for the applicant to provide an accurate approximation as to how many individuals this might be, however they estimate that 5-10 individuals may be booked in for appointments following telephone calls made to 20 individuals. Of these 5-10 individuals booked in, not all would consent. Therefore 's251' support will likely cover at least 3000 individuals, very likely more.
Data sources	**1.** Clinic lists at participating primary care and secondary care sites (This will have been created using Flag 4 data accessed for the purposes of clinical care) Secondary Care - Barts Health NHS Trust (Shrewsbury Road, Mile End, Whipps Cross) - open, recruiting - Whittington Health Trust - open, recruiting - Royal Free NHS Trust - open, recruiting - London North West University Healthcare NHS Trust (Ealing, Central Middlesex, Northwick Park) - in setup - North Middlesex University Hospital NHS Trust - in setup - Guy's and St Thomas' NHS Foundation Trust - in setup - Imperial College Healthcare NHS Trust (no longer participating in Dx)

	- University Hospitals of Leicester NHS Trust (no longer participating in Dx) Primary Care - Newham Transitional Practice - open, recruiting - Goodmans Fields Medical Practice - in set up - Dr CM Patel's Surgery - in set up - Shrewsbury Road Surgery - in set up - Mathukia's Surgery, Redbridge - in set up - Albion Health Centre, Tower Hamlets – in set up
Identifiers required for screening and invitation purposes	1. Medical record will be screened 2. Name 3. Date of Birth – for eligibility 4. Telephone number
Identifiers required for analysis purposes	1. N/A – analysis is undertaken with consent
Additional information	Data will be accessed directly from the clinic systems, with no data being copied to alternative systems, and no data will be taken off site or passed on to any third party.

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 develop a patient notification for RID-TB website, and participating sites, that contains a local opt out option, and provide to CAG for review.**

The applicant has provided a patient notification statement for the RID-TB website, which offers a local opt out, and explains the National Data opt out would be applied. The CAG were content with this response. Regarding developing notifications for participating sites, the applicant has not undertaken this part of the request, reasoning that this would not be seen by any of the relevant cohort, as they would not in fact be

patients at the time of being contacted, rather just members of the public. The CAG accepted this justification, noting that there was a notification on the RID-TB website, and that patients would be consenting into the study at the earliest possible opportunity.

2. **Please ensure the National Data Opt Out is upheld, and provide confirmation to CAG.**

The applicant has confirmed that the direct care team would apply the NDO prior to disclosing the list of people to call to the researchers. The CAG were content with this response.

3. **Please provide Favourable Opinion from a Research Ethics Committee regarding the amendment that will be submitted to cover the addition of the patient screening method requiring 's251' support, as per standard condition of support.**

The applicant has provided this, and this fulfils the standard condition of support below.

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: Original FO from the Harrow REC in January 2020, and amendment specifically including this CAG application provided FO on 18 August 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 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 about a practice.

f. 22/CAG/0099 - ABATED - Automated Brain Image Analysis for Timely and Equitable Dementia Diagnosis

Name	
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Dr Patrick Coyle	CAG vice-chair
Mr David Evans	CAG member
Professor Lorna Fraser	CAG member
Dr Harvey Marcovitch	CAG member
Ms Diana Robbins	CAG member
Mr Umar Sabat	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr Will Lyse	HRA Approvals Administrator

Context

Purpose of application

This application from Queen Mary University of London set out the purpose of medical research that seeks to investigate whether a new artificial intelligence technology can

be used to support more timely, accurate and equitable diagnosis of dementia within memory clinics.

Patients are referred to memory clinics if dementia is suspected. However, other conditions may cause memory difficulty and it is often difficult to know whether a patient has dementia when first assessed. This uncertain situation is referred to as “mild cognitive disorder” (MCD). Currently, the only way to establish a diagnosis of dementia is to follow-up patients over time to see if their condition worsens. This follow-up is often not available, and patients are discharged without a clear diagnosis. Brain scans are routinely used in memory clinic assessments as dementia causes shrinking of the brain. However, when humans interpret the scans, this only provides a clear diagnosis when the dementia is quite advanced. The applicants seek to test computerised interpretation of brain scans.

Two cohorts of patients with MCD, a retrospective cohort and a prospective cohort, will be identified from East London Memory Clinics. Patients in the prospective cohort will be identified from attendance at formulation meetings and MCD groups at East London NHS Foundation Trust (ELFT) Memory Clinics. Retrospective patients will be identified via electronic patient records at ELFT. Support is required to allow members of the research team, working alongside members of the direct care team, to identify patients suitable for inclusion in the retrospective cohort and link records held in ELFT. The core clinical dataset is recorded in a pseudonymised CRF. Patients NHS number will be deleted after linkage to scans to make CRF anonymous before transfer to the Queen Mary University of London for analysis.

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

Confidential patient information requested

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

Cohort	1200 patients:

	Prospective cohort of 200 patients who received an MCD diagnosis (outside the scope of support). Retrospective cohort of 1000 patients who had an initial diagnosis of MCD. The prospective cohort will include patients attending memory clinic between 01/06/2022 and 21/07/2023, and the retrospective cohort will include patients attending memory clinics from 01/01/2003.
Data sources	1. Electronic patient records at East London NHS Foundation Trust 2. Electronic patient records at Barts Health NHS Trust
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth
Identifiers required for analysis purposes	1. Gender 2. Ethnicity 3. Age

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. **Clarify whether members of the research team will attend the formulation meetings and MCD groups.**

a. **If so, support under the Regulations will be needed to provide a legal basis for any incidental disclosures of confidential patient information that may be made during these meetings.**

b. **If another legal basis is in place for these disclosures, this needs to be explained.**

The applicants confirmed that only members of the direct care team will attend clinical meetings where there is a risk of confidential patient information being disclosed without consent. The members of the direct care team who are part of the project will use this as a means of identifying which patients they should approach to seek consent. The CAG reviewed this information and raised no further queries.

2. **Feedback from any patient and public involvement discussions around the specific issue of use of confidential patient information without consent need to be provided. If this issue has not been discussed, further patient and public involvement needs to be undertaken and feedback provided to the CAG.**

The applicants provided further feedback from discussions with Hackney Caribbean Elderly Organisation and the Alzheimer's Research UK Network specifically around the use of confidential patient information without consent for this project. The CAG reviewed this information and raised no further queries.

3. **Confirm that further efforts will be made to promote the study, such as placing posters in relevant services and online.**

The applicants advised that posters advertising the project will be displayed in East London memory services, as well as publicising the project online through the Trust website as described in the application. The CAG reviewed 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:** 08 June 2022.

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

   The NHS Digital **2020/21** DSPT reviews for **East London NHS Foundation Trust and Bart's Health NHS Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 July 2022).

g. 22/CAG/0086 - The Norfolk Arthritis Register (NOAR)

Name	
Dr Tony Calland MBE	CAG Chair
Professor William Bernal	CAG alternative vice-chair
Dr Sandra Duggan	CAG member
Dr Rachel Knowles	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Ms Diana Robbins	CAG member
Mr Dan Roulstone	CAG member

Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of East Anglia set out the purpose of medical research that continues the Norfolk Arthritis Register (NOAR), which investigates and identifies the genetic and non-genetic factors which may be related to the onset of inflammatory arthritis, response to treatment and its long term outcomes.

The Norfolk Arthritis Register (NOAR) was set up in 1989 as a large community-based study investigating the cause and outcome of inflammatory polyarthritis. So far, data on over 4900 participants has been collected, and recruitment is continuing. The application was originally supported by the CAG under reference ECC 4-02(FT1)/2012. A refreshed application has been submitted at the request of the CAG.

All patients who are newly diagnosed with an inflammatory arthritis, presenting via primary or secondary care, should be referred to NOAR. New referrals are checked for eligibility and patients are then contacted by the study team by telephone and verbal consent sought to send out the study information. This information contains a consent form and participation would proceed on a consented basis.

The applicants will also undertake linkage to HES and ONS mortality data. The NOAR ID, NHS number, postcode, sex and date of birth for all identified NOAR patients will be extracted from the NOAR database. Two separate data extracts will be created, one list which will be processed under s251 and another list where patients have given explicit consent. Both lists will be transferred to NHS Digital for linkage to HES and ONS data. The National Data Opt-Out will be applied and the all identifiers other than the NOAR ID removed. The dataset will then be transferred to the University of Manchester Data Safe Haven.

The applicants seek support for the transfer of confidential patient information for newly diagnosed patients to the NOAR team, so that eligibility can be checked, and contact made. Support is also sought for the further access, retention and reuse of mortality

records supplied by ONS between 2003 and 2017 for patients recruited before 2003 or after 2015. Support is also sought for the further access, retention and reuse of HES data, supplied between 2000-2017 for participants recruited prior to 2015 who have not been reconsented. S251 support is also sought to provide an ongoing legal basis for participants who have died or been lost to follow up.

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

Confidential patient information requested

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

Cohort	Patients aged 16 years and over who meet the below inclusion criteria: Have had two or more swollen joints, lasting for 4 or more weeks. Have a clinician diagnosis of an Inflammatory Arthritis. Resident in Norfolk at time of symptom onset and registered with participating GP Practice. Onset in the last 2 years. Willing to give informed consent to take part in the study. 5330 are estimated to be included
Data sources	1. NOAR Participants (questionnaire data) 2. GP's within Norfolk and Waveney CCG 3. Norfolk and Norwich University Hospital NHS Foundation Trust patient and clinical data (PAS, ICE, patient notes) 4. NHS Digital data - a) Hospital Episodes Statistics (HES) b) Office for national Statistics (ONS) mortality data 5. European Prospective Investigation into Cancer (EPIC)

Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode – sector level 4. Sex
Identifiers required for analysis purposes	1. Postcode – district level

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. **Further justification is requested as to why non-responders need to be included.**

The applicants advised that they expected a response rate of only 50%, should patients be approached directly for consent. This would mean that significant number of NOAR participants were not included. The patients would have already provided clinical and biological data, potentially for up to 25 years, which is useful in determining the long-term effects of rheumatoid arthritis.

The applicants also noted a potential risk of bias, due to factors often associated with non-response, such as age, social deprivation, poor health, etc. The applicants also sought to make NOAR as representative as possible.

The CAG noted this 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:** 30 April 2015.

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

   Confirmed:

   The NHS Digital **2020/21** DSPT reviews for **University of Manchester, University of East Anglia, Norfolk and Norwich University Hospital NHS Foundation Trust and Norfolk and Waveney CCG** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20 June 2022).

2. New Amendments

a. 20/CAG/0069 – C&I CRIS Linkage with HES and Mortality

Name	**Capacity**
Professor William Bernal	CAG Alternate Vice Chair
Dr Pauline Lyseight-Jones	CAG Member
Mr David Evans	CAG Member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application was originally supported 14th September 2020. The outcome letter states support is in place to establish a research database linking the mental health records of patients treated within the Camden and Islington NHS Foundation Trust area with Hospital Episodes Statistics (HES) and ONS Mortality Data held by NHS Digital, and that the cohort is; '*patients of Camden and Islington NHS Foundation Trust with active records during the period from 1 January 2012 to 31 December 2018.*' It is estimated that 140,000 patients were included in the Camden and Islington NHS Foundation Trust CRIS database.

The original outcome letter does mention the creation of a control group, but the clarity surrounding if 's251' support was required for this is not clear.

No linkage has as yet been undertaken.

This amendment sought support for five changes and clarifications to the application. These are listed below.

Change 1: SLaM have migrated to a cloud-based server and storage solution through Microsoft Azure and, consequently, the C&I Research Database is now securely hosted on Microsoft Azure as well through SLaM. The C&I Research Database remains wholly separated from the rest of SLaM's network on Microsoft Azure. Therefore this amendment sought support to include Microsoft as a new data processor, although it is understood that Microsoft Azure is a sub-processor of SLaM. The applicant has also updated associated documentation to make this clear.

Change 2: Minimisation of SLaM's role as a third-party Data Processor for the purpose of data linkage, limited to only hosting data. This change is represented by a corresponding change of the data flow, as C&I will now undertake the linkage. An updated data flow diagram and other associated documents have been provided alongside this change.

Change 3: expansion of the case cohort – requested upon recommendation from NHS Digital. i.e, extending the cohort from the original 2012 -2018. Applicants confirm they now wish the patient cohort to be patients of Camden and Islington NHS Foundation Trust with active records during the period from 1 January 2012 - April 30 2022. The applicant confirmed this to be approximately 20,000 additional individuals.

Change 4: extension of linked outcome data received (regarding linkages with HES/ONS). Although in the original CAG outcome no end date was set for these linkages, NHS Digital have requested that this is clarified. The period of data the applicant is looking to link to continues to be a somewhat moving target – they wish to ask for as much "current" data as possible, up to the point when the data are actually extracted. This is because this is a one-off linkage, rather than an ongoing agreement. NHS Digital have previously requested no end date is set for these types of linkages, as they do not have a mechanism to set an end date, and must extract the outcome data until the present date/day the data is linked.

Change 5: **clarification of control cohort**

The applicants wish to clarify that the data linkage not only includes individuals identified as patients of Camden & Islington NHS Foundation Trust from 2012-2022, but also a matched cohort of non-patients resident in the London boroughs of Camden & Islington during this same time to serve as a control group.

This control group was mentioned in the original application and is referred to in the final outcome letter, but not in the sections surrounding what support is provided for, and who the cohort is. This amendment would therefore represent a large increase in the numbers of case controls whose confidential patient information is processed without consent.

The applicants requests HES/ONS linked mortality data for **all** individuals resident in the London boroughs of Camden & Islington from 2012-2022 to serve as a control group, but if this is not practicable, applicants wish to apply for at least 2 controls per case. They estimate that this would mean ~300,000 matched controls (i.e. individuals resident in the London boroughs of Camden & Islington who were <u>not</u> patients of Camden & Islington NHS Foundation Trust during the study period).

As part of queries prior to the meeting, the applicant confirmed that data coming back from NHS Digital for cases is planned to be; sex, ethnicity, full date of death, alongside BRCID. NHS number, name, and full date of birth will be removed by NHS Digital. The applicants already hold censored date of birth, (to 1st of the month as pre SLaM CRIS data rules), and LSOA. Support is required for this flow as full date of death is included, and the applicant is also able to reidentify as they already hold identifiable information in the database, and this can be linked back with BRCID. This support is already in place.

The applicant confirmed that data coming back from NHS Digital for controls is planned to be; sex, ethnicity, full date of death, LSOA and censored DOB to 1st of month, alongside encrypted HESID. Support is therefore required for this flow, due to the full date of death being included, and this is dependent on NHS Digital modifying the postcode to LSOA, and the Date of birth to the 1st of month, however the applicant has not had this confirmed from NHS Digital.

The applicant has also provided updated documentation to reflect the changes, including updated terms of reference, updated protocol, data flow diagram, leaflet, poster, which the CAG accepted.

Confidentiality Advisory Group advice

The amendment requested was considered by a Sub-Committee of the CAG in a meeting on 21st July 2022. This was because the amendment submitted contains substantial changes to the application. The CAG were content to recommend support for change 1, and change 2, noting that change 2 was less disclosive than the original design. The CAG were content to recommend support for change 3, as this is a reasonable request due to the length of time since support was originally provided. The CAG were content to recommend support for change 4.

Regarding Change 5, the receipt of linked HES/ONS outcome data from NHS Digital of a control group of residents of Camden and Islington. The CAG were not content to recommend support for this element. The CAG noted this is because they were not clear on the scope of support requested regarding the control group. It was not clear why the applicant required individual patient level data, as this had not been justified as part of the amendment application. If the applicant resubmits, they are to provide justification as to the added value of individual level data. The members also noted that the rationale for a control group in general had not been clearly provided, This should be provided as part of any resubmission.

Could the applicant receive aggregated data from NHS Digital, without any identifying information, and remove the requirement for CAG support? If the applicant received a modified date of death rather than full date of death, does NHS Digital consider that this would require 's251' support? The applicant is asked to discuss this with NHS Digital and confirm if there are any methods of receiving this data that would not require CAG support.

The Members noted that little information has been provided about how exactly the control group is identified, this should be further explained in a resubmission, if one is required after discussions with NHS Digital.

The CAG were not clear on the size of the control group, as the applicant has provided 2 options, one which was all individuals resident in the London boroughs of Camden & Islington from 2012-2022, and one of at least 2 controls per case. They estimate that this would mean ~300,000 matched controls. Noting that Camden has a population of around 240,000 and Islington around 230,000, and therefore even the 300,000 people is nearly the entire population of both boroughs. For any resubmission, the applicant should pick one option for the number of controls, and justify why this many is required.

The CAG noted that the patient notification was not aimed at any controls, and if 's251' support is required for this, then notification should also be developed to explain to controls what is happening with their data, and provide an opt out option.

The CAG also noted that as part of any resubmission, extensive patient and public involvement should be undertaken who are representative of the control cohort, to establish the acceptability of this use of confidential patient information without consent.

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 part of this amendment, and therefore advised recommending support to the Health Research Authority.

However, the receipt of HES/ONS linked data from NHS Digital regarding a matched cohort of non-patients resident in the London boroughs of Camden & Islington during the time period 1 January 2012 - April 30 2022 is not supported, and the applicant is

advised to re-submit an amendment for elements relating to the creation of the control group if required, to be considered at a full CAG meeting.

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **20/21** DSPT reviews for **Camden and Islington NHS Foundation Trust, South London and Maudsley NHS Foundation Trust & MHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 02 August 2022)

   The NHS Digital **21/22** DSPT reviews for **Microsoft UK** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 02 August 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **6 May 2022**

b. 21/CAG/0017 – Outcomes of Patients who survived Treatment on an Intensive Care unit for COVID-19 in England and Wales: a retrospective cohort study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from the Intensive Care National Audit and Research Centre (ICNARC) to

NHS Digital, NWIS (now known as Digital Health and Care Wales), NICOR at Barts Health NHS Trust, SSNAP at King's College London and the UKRR at the Renal Association, for the purposes of time limited linkage with clinical datasets in order for pseudonymised linked datasets to be disclosed to the applicants at the University of Oxford, and for the return of full date of death from NHS Digital and NWIS to the University of Oxford.

In this amendment, the applicants are seeking support to extend the duration of 's251' support until 31 July 2023, in line with a recent funding extension.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. The CAT raised no queries regarding this amendment.

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 Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for the following organisations have been assessed as 'standards met' by NHS Digital;**

- **University of Oxford**
- **ICNARC 8HN44**
- **NHS Digital**
- **NICOR**
- **SSNAP King's College London - Sentinel Stroke National Audit Programme EE133874-SSNAP**
- **UKRR (The Renal association) 8HQ50**

- **A CPiP assessment is in place for DHCW (previously NWIS).**

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   REC **Confirmed non-substantial 28 June 2022**

c. PIAG 1-05 (e) / 2006 - Frequency of follow-up for patients with low-, intermediate-, and high risk colorectal adenomas

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This amendment sought support for an end of study extension from 31 December 2022 to 30 June 2023 following a six-month no-cost extension approval to programme grant funding the study by funder, Cancer Research UK, to allow analysis to be completed.

It is additionally known from discussions with the applicant that ongoing 's251' support is required for 10 years after the end of the study. This is due to retention of full date of birth centrally (not with direct care team only). Full date of birth is required to be retained because it was used in the earlier parts of the analysis, and therefore is required to be retained for 10 years as per university policy. Therefore this amendment is to seek support to extend the end of the study until 30 June 2023 to allow complete analysis, however 's251' support is required until 30 June 2033.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

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 Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **21/22** DSPT review for **Imperial College London, Faculty of Medicine, Cancer Screening and Prevention Research Group** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 August 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 17 May 2022

d. 20/CAG/0157 – The Oxford Risk Factors And Non-invasive imaging Study: ORFAN

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to develop and validate novel imaging biomarkers to predict future heart attacks and other cardiovascular complications. Support is currently in place to allow the disclosure of confidential patient information from participating NHS Trusts to NHS Digital, Arden & Gem CSU (on behalf of the National Institute for Cardiovascular Outcomes Research (NICOR)), Kings College London (on behalf of the Sentinel Stroke National Audit Programme (SSNAP)), and local NHS Trust NIHR Biomedical Research Centres (BRC's) for the purposes of time limited linkage with clinical datasets, in order

for anonymised linked datasets to be disclosed to the applicants at the University of Oxford. Support is currently in place to use confidential patient information regarding 75,000 retrospective patients in the UK (England and Wales only for the purposes of CAG), who have undergone clinical Computed tomography angiography (CTA) scans or unenhanced computed tomography (CT) chest, abdomen and pelvis scans at participating NHS Trusts. The timescale for inclusion in the study is different for each collaborating NHS Trust, however, no patient with a scan before 2010 will be included in the study.

This amendment seeks support to include The Liverpool Heart and Chest Hospital NHS Foundation Trust as a new participating site (new data processor for CAG). The amendment also seeks support to include post mortem CT scans if they occurred, to ensure applicants can confirm scientific findings with scans performed after death associated with heart disease. CT scans are increasingly used for post-mortem investigation of cause of death. This is not an additional data flow, as 's251' support is already in place for this data flow, and it is not increasingly disclosive, however this is an additional data item.

The applicant has also provided updated patient facing documents which are accepted as notifications to CAG.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

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 Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed: All organisations processing confidential patient information, including the Trusts where patients are identified will be required to have security assurances in place. However, as there are more than five organisations, the CAT team will not check each one individually; it is the responsibility of the applicant to ensure these are in place.**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 07 July 2022**

e. 20/CAG/0138 – Avon Community Acquired Pneumonia Study (Avon CAP): A Pan-Pandemic Acute Lower Respiratory Tract Disease Surveillance Study

Name	Capacity
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from North Bristol NHS Trust and University Hospitals Bristol and Weston NHS Foundation Trust to the University of Bristol, in order to determine population-based incidence rates of hospitalized adults ≥18 of age with community-acquired lower respiratory tract infection (LRTI - including Community Acquired Pneumonia) in Bristol.

This amendment sought support to widen the cohort of patients to include those who attended the Emergency Department (but were not admitted to hospital), as the applicants realised these patients were an important subgroup that were currently not included.

Confidentiality Advisory Group advice
The amendment requested was considered by Chairs' Action. The Vice-Chair was content to recommend support for this amendment, and noted the clarifications of the applicant of 21/CAG/0173 (Avon-CAP GP2), surrounding the prevention of double counting between the two sister studies.

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

   The NHS Digital **2020/21** DSPT reviews for **University Hospitals Bristol and the Weston NHS Foundation Trust** & were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 10 August 2022)

   The NHS Digital **2021/22** DSPT reviews for **University of Bristol (Bristol Medical School) & North Bristol NHS Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 10 August 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 11 August 2022**

f. 15/CAG/0119 – MBRRACE-UK – Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Tony Calland, MBE	CAG Chair

Context

Amendment request

This Healthcare Quality Improvement Partnership (HQIP) commissioned activity from University of Oxford set out the purpose of the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP) which is a national programme that aims to assess quality and stimulate improvement in safety and effectiveness in maternal, newborn and infant healthcare by systematically enabling clinicians, managers and policy makers to learn from adverse events. Support under the Regulations was given to cover access to confidential patient information from ONS and NHS Trusts.

This amendment sought support to extend the duration of 's251' support in order to include patients treated between 1 January 2009 and 30 September 2025, in line with the extension of the contract with the commissioners, HQIP, as the applicant has been awarded the contract to continue to deliver the Maternal, Newborn and Infant Clinical Outcome Review Programme for three years, in the first instance, to 30 September 2025, with the possibility of two further years (to 30th Sept 2027) based on the successful delivery of the programme up to that point. The agreement between themselves and HQIP has been provided.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action, who was content to support the amendment.

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

   The NHS Digital **2020/21** DSPT review for **University of Leicester - College of Life Sciences (EE133832-CMBSP) was** confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 10 August 2022)

   The NHS Digital **2021/22** DSPT review for **Nuffield Department of Population Health, University of Oxford (EE133863-MSD-NDOPH-ND PH)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 10 August 2022)

g. 21/CAG/0081 – neoWONDER: Neonatal Whole Population Data linkage to improving long-term health and wellbeing of preterm and sick babies

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the Neonatal Data Analysis Unit (NDAU) at Imperial College London aims to improve the lifelong health and wellbeing of babies born preterm and/or with surgical conditions by linking existing data from the National Neonatal Research Database (NNRD) with routine health, educational and environmental datasets in England and Wales to evaluate the long-term impact of neonatal interventions.

This amendment sought support to clarify the linkage process regarding the National Pupil Database. Support is currently in place for NHS Digital to link confidential patient information (from NNRD) with the personal demographics service (PDS), and for NHS Digital to disclose confidential patient information alongside unique ID to ONS SRS in

order to link to National Pupil Database (NPD). However this was due to a misunderstanding during the application process. The applicant has now confirmed that as Department for Education undertake the linkage, 's251' support is in fact required for NHS Digital to disclose confidential patient information alongside unique ID to the Department for Education (DfE), rather than ONS-SRS, in order for DfE to link the clinical information to the National Pupil database, and provide a pseudonymised output to ONS-SRS.

The applicant has provided an updated data flow diagram, a letter of support from DfE, and the DfE linkage protocol.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

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 Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for these organisations have been assessed as 'standards met' by NHS Digital**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed no need to review 23 August 2022**

h. 19/CAG/0214 – Understanding the scale and nature of avoidable harm in prison healthcare (Phases 2 & 3: Case note review and qualitative interviews)

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from University of Manchester aims to determine the frequency and nature of avoidable patient harm in prison healthcare. There is currently support under the Regulations for researcher access to confidential patient information within electronic and paper-based medical records, managed by a number of healthcare providers delivering services at 17 named prisons in England. This will be the records of approximately 15,000 patients. Pseudonymised information will be extracted into an electronic case report form for analysis. A previous supported amendment is in place for an additional method of remote data collection via a locally agreed protocol with each prison/healthcare provider. This will be possible via the healthcare providers who can arrange access to prison-based records through their wider Trust/organisational secure servers. The study has support in place to access SystmOne patient records, and this is being done remotely due to the pandemic.

This amendment sought support for applicants to access ACCT (Assessment, Care in Custody and Treatment) documentation. ACCT is the case management system used to care for those in prison who are considered at risk of suicide and/or self-harm. This amendment has been submitted because Phase 2 of the study (screening and reviewing healthcare records) is now running entirely remotely, and applicants want to ensure that important suicide/self-harm information is not being missed. Originally, ACCT documents would have been accessed in the course of case reviews taking place at the prisons but in the course of screening records remotely, the nurses feel that it is likely that a lot of avoidable harm relating to self-harm and attempted suicide is being missed. This is because not all self-harm and attempted suicide is coded within SystmOne. Furthermore, unless the self-harm was severe enough to warrant a trip to A+E, there would be no discharge letter about it. ACCT documents are also not routinely uploaded into the healthcare system.

Therefore applicants are proposing additional steps within the data collection processes. Firstly, cross-referencing the census lists (all those in participating prisons

on a set census date) to find out who were on ACCTs during the census periods (i.e., 12 months prior to the census date) via HMPPS. Applicants will then access ACCT documents from those identified. Identifying who in the screening sample has been on an ACCT, and when, will ensure no cases of possible risk of avoidable harm are missed by the screening/reviewing processes. In addition, this amendment will enable applicants to comment specifically on the incidence of possible and actual avoidable harm in prison healthcare amongst adult prisoners who have been cared for by ACCT.

Confidentiality Advisory Group advice
The amendment requested was considered by Chairs' Action. The Chair recommended support for this amendment.

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 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:

   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.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 27 July 2022**

i. 21/CAG/0127 – The Oxford Vascular Study: a population-based study of the incidence and outcome of stroke, transient ischaemic attack, acute coronary syndromes and peripheral vascular events. Short title: OxVasc

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

The amendment, an administrative change to remove **University of Oxford - Medical Sciences Division - Nuffield Department of Population Health (**ODS EE133863-MSD-NDOPH-NDPH) as a data processor, and replace with **University of Oxford – Medical Sciences Division** (ODS 8HM11), is supported, subject to compliance with the standard conditions of support.

Amendment request

This amendment is an administrative change to correct the name of the data processor, as the DSPT was listed as an incorrect department of the University of Oxford

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this request.

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 Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS Digital **20/21** DSPT reviews for **University of Oxford –Medical Sciences Division** (ODS 8HM11) and **NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 19 August 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed as not requiring REC review 11 August 2022**.

j. ECC 4-03 (g)/2012 - General health and hospital admissions in children born after ART; a population-based linkage study

Name	Capacity
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants seek to extend the duration of support from 08 July 2022 to 31 August 2024. The additional time is needed as, due to NHS Digitals prioritisation of Covid-19 related research, the applicants have experienced delays in obtaining the required data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the extension was in the public interest.

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 Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold:
   Confirmed: NHS Digital and University College London - School of Life and Medical Sciences have confirmed 'Standards Met' on DSPT 2021/22 (be check of DSPT Tracker 02 August 2022).

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmation provided that this, non-substantial amendment, does not require REC review.

k. 20/CAG/0067– Learning Disability Mortality Review (LeDeR) programme

Name	Capacity
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The Learning Disabilities Mortality Review (LeDeR) programme reviews the deaths of all people with learning disabilities (aged 4 years and over) in England. The activity was previously given support under reference 16/CAG/0056. A new application was given support in May 2020 as the controller for the application had changed from HQIP to NHS England.

Currently, cases received on or before 31 December 2018 are included. The applicants seek to extend the processing timescale to include all cases reported from 01 January 2019 onwards, including current and future cases, with no specified end date.

The applicants also seek to allow staff from the North of England Commissioning Support Unit (CSU) and the South, Central and West Commissioning Support Unit

(CSU) to access the LeDeR data for the purpose of auditing the quality of reviews. The applicants noted that both CSU's are part of NHS England.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team, who agreed that the amendment was in the public interest.

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

   Confirmed: The NHS Digital **20/21** DSPT reviews for **Kings College London (EE133874-ROSALIND) and South Central and West Commissioning Support Unit (0DF)** were confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 28 July 2022).

   The NHS Digital **21/22** DSPT reviews for **University of Central Lancashire (EE133869-CBMS), North of England CSU (0AR) and NHS England (X24),** were confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 28 July 2022).

3. Amendments – Response to Provisional Outcome

a. ECC 6-02(FT3)/2012 - Sentinel Stroke National Audit Programme

Name	Capacity

Dr Murat Soncul	CAG Alternate Vice-Chair
Dr Martin Andrew	CAG member
Dr Malcolm Booth	CAG member
Dr Sandra Duggan	CAG member
Professor Lorna Fraser	CAG member
Mr Anthony Kane	CAG member
Mr Dan Roulstone	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor
Kaili Stanley	Stroke Programme Manager
Ellie McMullen	Programme Manager (SSNAP Operations)
Ms Marney Williams	patient representative

Context

Amendment request

This is a request to defer the national data opt out for ECC 6-02(FT3)/2012, non-research application. The Healthcare Quality Improvement Partnership (HQIP) commissions Kings College London to undertake the Stroke National Audit Programme (SSNAP).

SSNAP has been supported since 2012 with consistent submission of annual reviews since that time, however the data controller changed to Kings College London (from RCP) during that time period, but kept the same reference number.

Support is in place for clinical teams to provide the audit team with confidential patient information, which is linked with NHS Digital outcome data.

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 draft updated patient notification materials, which clearly describe the NDO would not be applied to ECC 6-02(FT3)/2012.**

The applicant provided patient notification materials, which the CAG considered, and were content described the non application of the NDO accurately.

2. **Please provide evidence of discussions with patients and the public, surrounding the non-application of the National Data Opt-Out.**

The applicant provided a report regarding patient and public involvement undertaken, and the CAG were now content that this evidenced support from patients and the public regarding the non application of the NDO to SSNAP.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided.

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. This outcome confirms a change to the original conditions of support. The National Data Opt-Out is not to be applied to patients included in the activities specified in ECC 6-02(FT3)/2012.

2. A local patient objection mechanism must continue to be used in relation to ECC 6-02(FT3)/2012.

3. The applicant is requested to submit a full refreshed application in relation to ECC 6-02(FT3)/2012 to ensure to scope of support is clear regarding non-

research activity. This should be submitted in lieu of the next due annual review.

4. The applicant is requested to submit a full new research application in relation to ECC 6-02(FT3)/2012 to ensure to scope of support is clear regarding research activity. This should be submitted in lieu of the next due annual review. These applications should be submitted together, so they can be reviewed alongside each other.

3. Annual Review Approvals

17/CAG/0196	Understanding local Heart Failure Pathways of Care
19/CAG/0208	Aetiology, timing and risk factors for tuberculosis-associated deaths in London: a retrospective, case-control study
20/CAG/0086	YouScreen
CAG 1-03(PR3)/2014	Next Steps previously known as Longitudinal Study of Young People in England (LSYPE)
ECC 5-07(b)/2009	Prescription-Event Monitoring
20/CAG/0038	The short and long-term cardiovascular consequences of critical illness: The C3 Study
20/CAG/0054	Screening for Hypertension in the INpatient Environment
ECC 4-03(g)/2012	General Health & Hospital Admissions in Children Born after ART: A Population Based
21/CAG/0074	CQC 2021 Community Mental Health Survey - Mixed Methods stand alone pilot
20/CAG/0045	An evaluation of a water fluoridation scheme in Cumbria: A population based comparative cohort study of systemic and topical fluoride exposure
20/CAG/0046	An evaluation of a water fluoridation scheme in Cumbria: population based comparative cohort studies of topical fluoride exposure alone
18/CAG/0064	National Bone and Joint Infection Registry

16/CAG/0063	aTTom Extended – Extended follow up of patients enrolled in the Adjuvant Tamoxifen Treatment – Offer More?
ECC 8-04(b)/2013	Road Accident In-Depth Studies (RAIDS)
21/CAG/0081	neoWONDER: Neonatal Whole Population Data linkage to improving long-term health and wellbeing of preterm and sick babies
ECC 3-04(f)/2011	Information Governance Clinical Dataset Linking Service
19/CAG/0182	National Joint Registry – Research Database
18/CAG/0015	Improving diagnosis and management in dementia with Lewy bodies using the CPFT Research Database (CRATE).
16/CAG/0006	UK National Flap Registry (UKNFR)
15/CAG/0176	Predictors and prevalence of genital Chlamydia trachomatis
ECC 2-06(n)/2009	National Cardiac Arrest Audit (NCAA)
18/CAG/0072	NHS Improvement Getting It Right First Time (GIRFT) Programme – Litigation Claims data
21/CAG/0106	TRIM: What Triage model is safest and most effective for the management of 999 callers with suspected COVID19? A linked outcome study
21/CAG/0137	IBIS II O: Long term observational follow up of previous participants of the IBIS II studies: DCIS and Prevention
21/CAG/0108	BRIGHTLIGHT_2021
18/CAG/0071	Avoiding Cardiac Toxicity in lung cancer patients treated with curative-intent radiotherapy to improve survival
ECC 7-05(h)/2011	CRANE
17/CAG/0025	Liver transplantation as treatment for patients with hepatocellular carcinoma; a study using existing electronic data
PIAG 6-06(c)/2008	Evaluation of the HPV Vaccination programme and its impact on the cervical screening programme

21/CAG/0090	PICANet (non research)
21/CAG/0098	PICANet (research)
20/CAG/0103	National Haemophilia Database (NHD) (research)
20/CAG/0102	National Haemophilia Database (NHD) (non research)
21/CAG/0093	Facilitating access to online NHS primary care services - current experience and future potential (Di-Facto)

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Dr Murat Soncul & Professor William Bernal, CAG Alternate Vice-Chairs,	*03 November 2022*
& Ms Clare Sanderson, CAG Alternate Vice-Chair	*07 November 2022*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*28 October 2022*