Minutes of the meeting of the Confidentiality Advisory Group

12 May 2022 via Zoom

Present:

Name	Role
Dr Murat Soncul (AVC)	CAG Alternate Vice Chair
Professor William Bernal (AVC)	CAG Alternate 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

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Ms Emma Marshall	Confidentiality Specialist
Dr Paul Mills	Senior Confidentiality Advisor/Service Manager
Mr Michael Pate	Confidentiality Advisor
Ms Caroline Watchurst	Confidentiality Advisor
Ms Stephanie Macpherson	Approvals Operations Manager, HRA (Observer)
Ms Hannah Allende	Deputy Research Governance Manager, University Hospitals Plymouth NHS Trust (Observer)
Ms Sally Gregory	Senior Clinical Research Associate, NAMSA (attending as applicant for part of SDDR pilot – item 3a only)
Ms Lindsay Cunningham	Research Radiographer, Wrightington Hospital (attending as part of SDDR pilot – item 3a only)
Ms Lana Bojanić	Research Assistant & PhD candidate, Co-Investigator, University of Manchester (attending as part of SDDR pilot – item 3b only)
Dr Alison Baird	Research Associate, Co-Investigator, University of Manchester (attending as part of SDDR pilot – item 3b only)

1. Introduction, apologies and declarations of interest

CAG member Mr Dan Roulstone gave his apologies.

The following conflicts of interest were declared;

- COI – CAG Member Professor Lorna Fraser has a conflict with the 22/CAG/0071 (4b) – one of her team members is a co-applicant on the study

- COI – CAG alternative Vice-Chair Professor Will Bernal has a COI with 22/CAG/0073 (4c) – he works closely with the renal team at KCL

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **07 April 2022** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **07 April 2022** meeting applications.

3. New applications – Research (SDDR pilot)

a. 22/CAG/0075 - SMR Reverse HP Study

Context

Purpose of application

This application from NAMSA on behalf of Lima Corporate is submitted to undertake medical research to prospectively and retrospectively collect data from the medical records of patients who were treated with either the polyethylene glenosphere shoulder replacement compared to the cobalt chromium metal glenosphere shoulder replacement between 1st January 2013 and 1st January 2020 at Wrightington, Wigan and Leigh NHS Foundation Trust.

The purpose of the research is to gather data from assessments and images collected at hospital visits performed as per standard of care from pre-op to 2-year follow-up. Data will be analysed to measure the safety and effectiveness of the devices, both of which are CE-marked and widely used in Europe. The data may be used to submit to other geographies where the device is not currently approved for use. Measure of the safety and effectiveness of the device will determine if the device is in the continued public interest to be used in shoulder replacement surgery. The data may be submitted to other markets with a view to improving patient care in those countries.

The data from an estimated 140 medical records will be accessed by the research delivery team (who are not considered part of the direct care team at the Trust) to search for eligible patients, pseudonymise their data, and enter this into the sponsor database and burn pseudonymised X-rays to CD for review by an independent radiographic reviewer without patient consent.

It is anticipated that due to the COVID-19 pandemic, some patients may not have completed their 2-year follow-up. For patients where it is less than 36-months since surgery and they haven't been discharged from the care of Wrightington Hospital, patients will be sent an invitation for a follow-up appointment along with the Patient Invitation Letter, Patient Information Sheet and Informed Consent Form to invite them to participate in the research. Where it is more than 36-months since surgery and the patient hasn't been discharged from the care of Wrightington Hospital, patients will be sent a Patient Invitation Letter, Patient Information Sheet and Informed Consent Form telling them about the study and inviting them to consent to participate.

A recommendation for class 1 and 3 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

Cohort	All patients treated with the SMR Reverse Shoulder System device (either with 36-mm CoCrMo (cobalt chromium molybdenum alloy) glenosphere or 40-mm cross-linked UHMWPE (ultra-high molecular weight polyethylene) glenosphere) at Wrightington Hospital between 01Jan2013 and 01Jan2020 providing the patient has not opted out of research participation and listed in the MESH database.

Data sources	1. Medical Records
Identifiers required for linkage purposes	1. Name 2. Address 3. Telephone Number 4. Date of birth 5. Date of death 6. NHS number 7. Hospital Number
Identifiers required for analysis purposes	1. Year of birth 2. Date of death 3. Gender 4. Ethnicity
Additional information	Date of birth required to be able to link the unique Subject Identification Number with the patient. This will only appear on a Subject Identification Log kept at Wrightington Hospital. Patient date of birth will not appear on any data leaving the hospital. Only the year of birth will be required for entry into the database to determine the patient age at surgery and any correlations between age and device effectiveness and safety outcomes.

Confidentiality Advisory Group advice

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

Public interest

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

The CAG agreed that the application had a medical purpose. However, members noted concerns around the public interest and were unclear on how this activity (which is based on the use of NHS data) would be of benefit to the NHS.

Practicable alternatives

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

- **Feasibility of consent**

Since some patients will have completed the 2 year post-operative follow-up around 7 years ago, some patients will have died or relocated. The applicant advised that attempts to make contact with patients may pose a greater risk of a breach of confidentiality than allowing the research delivery team access to the medical records for pseudonymisation and data extraction for the purposes of the study.

The applicant advised that in order to obtain a powered data analysis, full ascertainment of the potentially available data is required and that although Patient Invitation Letters, Patient Information Sheets and Informed Consent Forms could be posted to all eligible patients, the risk of non-response is too great, and in the case of non-response, dissent then has to be assumed resulting in analysis of the data being impossible and not statistically viable.

The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Identifiable data is accessed by the research delivery team at Wrightington, Wigan and Leigh NHS Foundation Trust to allow them to identify eligible patients for the study. Data is pseudonymised by the research delivery team before providing to the sponsor.

The CAG highlighted that the data required for this study could already exist in the National Joint Registry (NJR). The applicant was asked by the CAG during the meeting if this option had been explored. The applicant was unsure of the level of detail included in the NJR and indicated that this option had not been explored fully. The CAG would like to see confirmation that the NJR has been contacted to discuss if this information is available.

Justification of identifiers

The applicant advised that name, NHS number, date of birth and date of death will be used for linkage purposes. The CAG suggested that this is reduced to NHS number, date of birth and either month or year of death.

The CAG noted concerns with collecting and retaining the address and telephone number of the entire cohort of the study. Members agreed that the address and telephone number should only be collected and retained for the prospective cohort of patients.

The CAG considers date of death as an identifier and therefore noted concerns with sharing the date of death with the sponsor. Members agreed that sharing the month or year of death with the sponsor would preferable.

Members agreed that further clarity was needed regarding which identifiers were being retained and the length of time for retention.

‘Patient Notification’ and mechanism for managing dissent

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

The CAG noted concerns with the lack of study specific patient notification and option for a local opt-out mechanism (although members noted that the National Data Opt-Out would be applied). The applicant was asked during the meeting if there was any planned study specific patient notification and local opt-out mechanism. The applicant commented that she had discussed this with the lead for the Trust’s patient participation group. The applicant went on to explain that the lead was aware of the lack of study specific patient notification and local opt-out mechanism and was in favour of implementing this but due to imminent retirement this piece of work had not currently been carried forward.

The CAG also noted concerns that the Patient Information Sheet did not provide enough information about data being shared with countries outside the UK.

Patient and Public Involvement and Engagement

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

The CAG was appreciative of the efforts that had been made by the study team to undertake patient and public involvement (PPI) and to include a detailed response in

their application in relation to this work. However, the CAG noted concerns with the high number of negative responses in relation to accessing confidential patient without consent for this study but noted that this may be linked to the way that the questions had been presented to the group. The CAG would therefore like to see more work undertaken in this area. Members noted that although PPI work had been undertaken with 5 representatives from the Trust's Patient Research Advisory Group this should be broadened to seek the views of patients with experience of joint replacement surgery. Members suggested that approaching arthritis research charities or the National Orthopaedic Centre could be helpful in finding patients with relevant experience.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

Number	Action Required	Response from the applicant
1.	CAG requires the applicant to clearly demonstrate how there will be a clear public benefit arising from the use of information without consent. CAG members were unclear about how this activity (which is based on the use of NHS data) would be of benefit to the NHS. • Please provide further clarity on how this activity will be of benefit to the NHS.	
2.	It should be clearly demonstrated that steps have been taken to minimise the use of identifiable data to conduct the activity.	

	• Please confirm if the collection and retention of names and addresses could be reduced from the entire study cohort to the prospective cohort of patients only.	
3.	Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available. The CAG highlighted that the data required for this study could already exist in the National Joint Registry (NJR). • Please confirm with the NJR if the data required is available and provide evidence of their response.	
4.	The CAG considers date of death as an identifier and therefore noted concerns with sharing the date of death with the sponsor. • Please confirm that date of death could be reduced to either month or year of death.	
5.	Please provide further clarity on which identifiers are being retained and the length of time for retention.	
6.	It is a general principle of CAG support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. The CAG noted that patient notification specific to the study did not appear to be in place. The CAG also noted that although the National Data Opt-out will be applied a local opt-out mechanism was not in place. • Taking these points into account please provide details of plans to	

	implement study specific notification and a local opt-out mechanism, including copies of any new or updated patient notification materials.	
7.	Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead. The CAG noted that although PPI work had been undertaken this should be broadened to seek the views of patients with experience of joint replacement surgery. The CAG also noted a high proportion of negative responses in relation to accessing confidential patient without consent for this study but felt that this may be linked to the way that the questions had been presented to the group. • Taking these points into account please provide details of plans to undertake further PPI with patients with experience of joint replacement. The CAG suggests exploring different methods of undertaking PPI to enable the group to understand the questions being asked. The CAG also suggests that approaching arthritis research charities or the National Orthopaedic Centre could be helpful in finding patients with relevant experience.	

Specific conditions of support (provisional)

The following sets out the specific conditions of support.

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

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

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

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.

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 National Drug Treatment Monitoring System (NDTMS) and Welsh National Database for Substance (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, DHCW and PHS 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.

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 serious incident reports (SUI) 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.

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) **Controls:** OHID/DHCW/PHS will create a control group of people who have been in contact with drugs and alcohol services in the year prior to the death of the matched case – and were alive between 1st October 2021 and 30th September 2022. The control group will aim to have at least 2 matched controls per case, as confirmed by the applicant.

	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	5. Gender 6. Ethnicity 7. 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 The applicant received quarterly updates from ONS with regards to the **PIAG-4-08(d)/2003** application.

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

Public interest

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

The Members were very supportive of this application, and agreed this was an important study which was very much in the public interest.

Scope

The CAG discussed the scope of 's251' support required between themselves, and also with the applicant. The Members were clearer on the data flows after the discussion, however, the CAG requested that an updated data flow diagram be submitted for clarity, and to confirm their understanding of the outcome of the discussions. The Members requested that this data flow diagram should provide a clear explanation of the data flows for each country, including which data items were disclosed, and provide the same regarding the 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 basis under common law relied upon for each dataset, for example, the Welsh National Database for Substance Misuse (WNDSM) data.

Practicable alternatives

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

- **Feasibility of consent**

The study is unable to obtain direct informed consent as the individuals in question are deceased. The CAG were content with this reasoning.

The applicant has confirmed that it would be impractical to obtain consent from the living control group due to time and resources available, and the applicants reason that if they were able to contact living people to ask for consent, their differential response rate would create selection bias. For example, based on population surveys, it might be expected that younger individuals to be less likely to respond and be included in the study. This would mean that any comparison with people who had died and any

estimates of therisk of suicide will be inaccurate. Applicants need to analyse data on the total sample of living people to ensure findings are robust.

During the CAG meeting, the Members further queried this point. The applicant explained further that as they are looking at a case vs control cohort comparison of specific dates, it is important that the control group are selected from the correct time point. If asking for consent, this comparison between groups of individuals during the same time period would not be possible, and create a potentially biased sample. The CAG accepted this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage. The Members agreed that the use of anonymous or pseudonymous informaiton for linkage was not a practicable alternative.

'Patient Notification' and mechanism for managing dissent

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

The case cohort are deceased, and the CAG accepted that it is therefore not possible to opt out. The CAG confirmed that some form of notification is required for the controls. The applicants have provided an information sheet for this purpose to inform alcohol and drug service users that their data is being used in a study of suicide. They stated this will be included on NCISH and drug and alcohol misuse services data holders websites. However no study specific opt out option is currently available for the control group.

Regarding control cohort, applicant reasons that the national data opt-out is applied prior to data being entered onto the NDTMS, WNDSM, DAIsy and therefore this data would not be held on these databases and would not be shared with NCISH. However, the CAG are aware that this is not the case, as NDTMS is a consented data collected, and the NDOO does not apply. NDTMS have previously confirmed to CAG that they were unable to apply the NDOO to this database as they do not retain NHS number.

The CAG considered that if the control group were not going to be consented, then they should be provided the opportunity to opt out. This should be possible to manage via NDTMS, and the applicant is requested to communicate with NDTMS about the possibility of managing a study specific opt out for the control group.

Additionally it was noted that although the applicant had stated this would be displayed online on the NCISH website, and on drug and alcohol service providers websites, the CAG felt it should also be displayed on the NDTMS website, and that the applicant should also develop a poster for display on site at drug and alcohol service sites.

The Committee also noted that the notification leaflet was currently not very accessible to lay individuals. The application indicated that it had been reviewed by patients, however the CAG consider that this needs to 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.

Patient and Public Involvement and Engagement

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

The applicant confirmed that they received one-off input from two people with lived experience of alcohol and drug services, one of whom was a carer, who revised the study documentation.

The applicant is in the process of establishing a study advisory panel which includes two members of the lived experience panel who have experience of alcohol and drug services, and will also include Samaritans, alcohol and drug service professionals, Commissioners, Primary Care.

It does not appear that the use of confidential patient information without consent has been properly discussed, regarding either the deceased cohort, or the control group. The Members felt that the Patient and Public Involvement undertaken was limited, and that 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. The CAG suggested that there may be voluntary sector organisations who may have Patient and Public Involvement participants who were willing to engage in discussions.

Exit Strategy

The total duration of the study will be 18 months. The applicant stated that the exit strategy is pseudonymisation. 's251' support required until OHID and DHCW delete the key between NCISH identifier and confidential patient information, and it appears this is estimated as 31 March 2023.

The CAG queried the applicant regarding the retention of the NCISH ID attached to the linked dataset, which in turn meant that it would be technically possible for the applicant to re-identify these individuals, as they hold the linkage key in a separate database. The applicant initially responded that they would not delete the NCISH ID as this was required to cross check about those who were in touch with mental health services. The CAG noted that it was not clear if this was part of the application. The applicant should clarify is 's251' support is required for this element, or if an amendment will be submitted for this at a later date. The Members then suggested that perhaps the NCISH ID could be deleted after this further linkage was undertaken, which the applicant agreed would be possible.

During this discussion it transpired that full date of birth and full date of death were planned to be retained in the final database for analysis, and it was unclear why this was required. The applicant confirmed that the full date of birth can be modified and deleted, and the full date of death can also be reduced and deleted. Once the full date of birth, full date of death, and NCISH ID are deleted from the dataset, 's251' support will no longer be required. The applicant is therefore requested to clarify if linkages to further datasets not currently listed also represent part of the requested support, and to clarify at which time point the NCISH ID, full date of birth, and full date of death will be deleted from the dataset, and in doing so, clarify the exit strategy from support.

Confidentiality Advisory Group advice conclusion

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

Request for further information

Number	Action Required	Response from the applicant
1.	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 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.	
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.	
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.	
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.	
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.	
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.	

Specific conditions of support (Provisional)

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

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

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.

4. New applications

a. 22/CAG/0070 - MYO-Guide: a machine learning approach to the analysis of MRI

Context

Purpose of application

This application from Newcastle University (with the controller for the activity confirmed to be the same) set out the purpose of medical research which aims to create an improved version of a machine-learning algorithm called MYO-Guide.

Most clinicians are not specialised in identifying muscle disease type from MRI image and NGS has several well-documented limitations. Therefore, a tool that can accelerate an accurate diagnosis will have a clear impact in the medical and patient communities. Specifically, a tool that uses machine learning to automatically segment muscle regions, analyse the amount of fat present on an MRI, and suggest a list of potential diagnoses could greatly facilitate the diagnosis process.

This study aims to create an improved version of MYO-Guide to analyse a larger number of muscle diseases, which will include an automatic segmentation tool to identify and delineate all muscles and automatically quantify the muscle fat replacement using Lamminen-Mercuri scale.

Support is requested to allow the disclosure of confidential patient information from NHS medical records and NHS research records to NHS computers. This will be name, NHS number and date of birth for the purposes of tracking patient data recruitment and ensuring that a patient is not included more than once. The research teams at sites will include both clinicians and research staff who are not part of the direct care team. To ensure the study is undertaken efficiently we will need the support of the research staff to help search patient medical records to find eligible patients. Therefore, support is requested for research staff who are not part of the direct care team to access name, NHS number and date of birth to search for eligible patients in NHS medical and research records.

Patient data and MRI scans will be transferred from sites to the MYO-Share platform; however, the data and scans will not contain any identifiers, and thus the transfer falls outside of the scope of support.

Only the 3 sites within England fall under CAG remit. The 15 sites outside of the UK fall outside of the scope of support.

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	Images and data from 200 participants aged one day or older with at least one of 25 selected neuromuscular diseases across 3 UK NHS sites.
Data sources	**NHS sites** - Medical records - Research study records
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth
Identifiers required for analysis purposes	None
Additional information	

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The CAG was clear of the cohort that was to be included in the research. However, it was not clear what date range the data collection covered.

The CAG would like confirmation of the date range over which records will be accessed and whether some of these records would be from patients who had died.

Practicable alternatives

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

- **Feasibility of consent**

With respect to the alternative of taking consent, the research team has said that it is no different to the data being collected from adult participants. It will not be practicable to obtain consent from this or any of the patient groups.

The CAG did not consider this to be an adequate explanation and it was not clear about what effort would be needed to take consent. Given that there were 200 participants across 3 centres, a stronger case for not taking consent was required.

The CAG considered that a more detailed rationale for not taking consent from participants or a child's parents/caregivers was required. It was recommended that PPI with a patient group might provide reasons why consent was not feasible.

- **Use of anonymised/pseudonymised data**

Name, NHS number and date of birth are required for the purposes of tracking patient data recruitment and to ensure that a patient is not included more than once. It would not be possible to do this by anonymising the data.

The research team is currently made up of two people who are part of the direct care team. They are the Chief Investigator, Prof Jordi Diaz Manera and Dr Carla Bolano Diaz. As busy clinicians they do not have time to search for eligible patients and collect data on a day to day basis. This work can be done more efficiently, and cost effectively, by trained members of the research team.

The CAG accepted the explanation that trained members of the research team could more efficiently search for eligible patients and collect data.

Justification of identifiers

The CAG understood that name, NHS number and date of birth were being accessed to prevent duplication of records and to track patient recruitment. The CAG also noted that identifiers were being retained for 10 years after the study ends.

The CAG requested justification for the identifiers that were being used to track patient recruitment, alongside reasoning for keeping these identifiers for 10 years after the study ends. This specifically relates to the use of the participant's name, in addition to NHS number and date of birth, as two of these identifiers should be sufficient to achieve the aims of the study.

'Patient Notification' and mechanism for managing dissent

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

Study posters will be hung in relevant clinics at UK sites to inform patients about the study and how their data will be used. The posters will also provide contact details for further information to opt out of their data being included in the study.

If a patient objects to their data being used in the study this will be recorded on the Excel spreadsheet that is used to track recruitment into the study. This is to ensure all the relevant information regarding a patient and their data is in one place. This will ensure the research team does not include the patient's data in the study after they have opted out of their data being used in the study.

The applicant has justified the above process by saying, "There is a difference between using someone's data in a study and storing a person's personal information. If a person opts out of the study, then their age, sex, genetic diagnosis, Lamminen-Mercuri score and MRI, will not be used in the analysis. However, if we remove their name, DOB, NHS number from our recruitment tracking database there is the potential that a research team member searching patient databases includes the patient in the study again because there is no longer a record to cross reference. This could be less considerate of the patient's wishes because in this scenario, the patient has opted out, we completely remove them from the recruitment and data collection database, a research team member in the future searches patient databases and again finds the patient and adds them to the study databases not realising they requested opt out.

Where someone dissents, using the two separate spreadsheets the research team will be able to link the patient's study data to their personal data. They will use their personal information to find their unique study identifier and then remove the related data from the data spreadsheet. A note will then be placed on the recruitment spreadsheet to say this person has opted out. Data will not be removed from the analysis after recruitment has finished and analysis has begun.

The National Data Opt-Out will not apply to this study; rather a local opt-out will be used. The poster will provide the contact details of the local research team. The research team will follow the steps outlined in the paragraph above to remove the related data.

The CAG considered the proposed notification and opt-out mechanism.

The CAG did not consider the language of the poster to be appropriate for children. The poster needed to be much clearer on the medical purpose of the study, the fact that CAG support was in place, and what that meant, and contain a method of local opt-out, including a specific local contact for any queries, rather than a generic email address.

The CAG believed that the method of local opt-out needed to be more clearly described.

The CAG requested justification as to why the National Data Opt-Out was not being applied to the study.

The CAG requested justification as to why someone's identifiable data was being kept even where they had dissented to the study.

Patient and Public Involvement and Engagement

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

This project has been reviewed by members of the Spanish Pompe Association and the Spanish Association of patients with Glycogenesis. The associations reviewed the original study proposal, as sent to the funder. They commented on it and were able to ask questions. This was done by mail. Moreover, the research team presented the project at the annual meetings and patients had the opportunity to ask questions and provide input.

The research team are planning to present the project at the next meeting of the UK Association of Patients with Glycogenosis to discuss the project with the patients and ask for their input.

The CAG was disappointed that, to date, no PPI had been conducted with any UK patient groups. It is likely that a patient group exists for all 24 conditions involved in the study, and so targeted PPI would be possible.

The CAG requested that PPI was conducted with a UK-based PPI group which represented one or more of the conditions under study. This is because attitudes towards the use of confidential patient information without consent may be country specific. The PPI should be undertaken both with parents and with older children / young adults who have experience of the conditions concerned. The findings should be presented back to the CAG, including the demographics of the group, the PPI conducted and the results of the specific study activities that involve using confidential patient information without consent.

Exit strategy

The researchers explained that patient information will be kept for 10 years. This is because there is potential for follow on studies. It would be an inefficient use of researcher time and study funds to search patient databases again to find eligible patients.

The CAG disagreed with the rationale for keeping patient information for 10 years. The CAG would like identifiers to be destroyed at the end of the study with separate applications being made for any future studies.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Please provide confirmation of the date range over which records will be accessed and whether some of these records would be from patients who had died.

2. Please give a more detailed rationale for not taking consent from participants or a child's parent/caregiver.

3. Please provide justification for the identifiers that were being used to track patient recruitment, alongside reasoning for keeping these identifiers for 10 years after the study ends. This specifically relates to the use of the participant's name, in addition to NHS number and date of birth, as two of these identifiers should be sufficient to achieve the aims of the study.

4. Please amend the poster so it is much clearer on the medical purpose of the study, the fact that CAG support is in place, and what that means, and contain a method of local opt-out, including a specific local contact for any queries, rather than a generic email address.

5. Please describe the method of local opt-out more clearly.

6. Please provide justification as to why the National Data Opt-Out was not being applied to the study.

7. Please provide justification as to why someone's identifiable data would be kept, even where they had dissented to the study.

Specific conditions of support (provisional)

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

1. That PPI was conducted with a UK-based PPI group which represented one or more of the conditions under study. The PPI should be undertaken both with parents and with older children / young adults who have experience of the conditions concerned. The findings should be presented back to the CAG, including the demographics of the group, the PPI conducted and the results of the specific study activities that involve using confidential patient information without consent.

2. Confirmation that you agree for identifiers to be destroyed at the end of the study with separate CAG applications being made for any future studies.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 09 May 2022**

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

   The NHS Digital **20/21** DSPT review for **University College London Hospitals NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 May 2022)

   The NHS Digital **20/21** DSPT review for **Great Ormond Street Hospital for Children NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 May 2022)

   The NHS Digital **20/21** DSPT review for **Northern Care Alliance NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 May 2022)

   The NHS Digital **20/21** DSPT review for **Newcastle University** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 May 2022)

b. 22/CAG/0071 - CHARMER

Context

Purpose of application

This application from the University of Leicester (with the controller for the activity confirmed to be the same) set out the purpose of medical research which aims to develop and test a way to support geriatricians (doctors working on older people's medicine wards) and hospital pharmacists to proactively deprescribe for older people whilst they are in hospital.

Research shows that almost half of older people in hospital are prescribed a medication with a risk of harm, but these medicines are rarely stopped. The reasons why geriatricians and hospital pharmacists do not proactively deprescribe for older people have been ascertained in a previous study. The research team has used this work to develop an intervention to support and encourage proactive deprescribing and will test this in this feasibility study.

Four hospitals in England will take part – geriatricians and pharmacists at 3 hospitals will receive the intervention and those at the 4th will not - they will be the control hospital. The intervention will be tested for 4 weeks.

Support is requested to allow the disclosure of confidential patient information from NHS medical records to Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH).

NNUH will transfer NHS number, date-of-birth, postcode, and a study ID to NHS Digital for linkage to NHS Digital-held datasets.

NHS Digital will use NHS number, date of birth and postcode to link to Hospital Episode Statistics, ONS Mortality data and NHS prescription data.

Data will be collected for each patient up to 3 months post discharge from the baseline hospital admission. Data end point will be 4 months after active study window end date to ensure that complete data for the maximum number of patients can be collected.

Routine data from Trust medical records will be collected for all patients receiving care from a recruited geriatrician during the 4-week active study window. This will be collected by a member of the direct care team and therefore, access to these identifiers in NHS medical records is out of scope of support.

After NHS Digital has linked the data, it will be anonymised prior to transfer to the Norwich Clinical Trials Unit by removing all identifiers and replacing with a study ID. Therefore, support is not required for transfer from NHS Digital to the Norwich Clinical Trials Unit, as there are no identifiers flowing.

Some of the patients under the care of a participating geriatrician will consent. These patients will have their NHS number, date of birth and contact details transferred from NHS sites to their GP practices to collect GP data. Consent is the legal basis for transfer of these identifiers, and this is therefore outside of the scope of support.

Where these patients consent to completing PROMS questionnaires, their name and contact details will be transferred to the Norwich Clinical Trials Unit for onward transfer to the CHARMER study team, for the purposes of arranging follow-up questionnaires to be sent. Consent is the legal basis for transfer of these identifiers, and this is therefore outside of the scope of support.

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

Confidential patient information requested

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

Cohort	All patients under the care of a participating geriatrician on a study ward during the active study window who do not consent to the study. This will be approximately 29 people per site out of 100.
Data sources	<u>NHS sites</u> 1) Medical records <u>NHS Digital</u> 1) Hospital Episode Statistics (June to October 2022) 2) ONS Mortality Data (June to October 2022) 3) NHS Prescription Dataset (June to October 2022)
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. None

Additional information	

Confidentiality Advisory Group advice

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

Public interest

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

Practicable alternatives

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

- **Minimising flows of identifiable information**

NHS sites could provide identifiers to NHS Digital directly, rather than having to send them to NNUH prior to transfer. However, NHS Digital agreed that NNUH should be used as a central site. Email correspondence from NHS Digital dated 17 February 2022 is enclosed with the application.

The CAG considered that because of the small numbers of participants involved, that using a central site was acceptable.

- **Feasibility of consent**

The research team need to collect relevant data regarding the care that participating geriatricians and pharmacists deliver to all patients under their care. Consensus amongst the research team of geriatricians and pharmacists is that it will not be possible to seek consent from all patients for this required data; for example some patients may be discharged before they can be approached by a member of the hospital research team. This is supported by the research team's previous research in a comparable patient population, which demonstrated that 29% of patients could not be approached for consent prior to their discharge from hospital.

The CAG wondered if there was a method by which those 29% of patients could be reached earlier, in order for them to provide consent, but was content with the explanation provided and were happy to accept it.

‘Patient Notification’ and mechanism for managing dissent

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

A poster and leaflet will be clearly displayed in participating study wards throughout the study window period to publicise the study to patients whose data will be included. In response to REC recommendations the poster has been updated to signpost the reader to the leaflet which provides more detailed notification information on the proposals and clear opt out guidance.

In addition, the leaflet will be included in hospital discharge documentation for all patients who have received care on one of the study wards during the study window, so patients have a copy of study information and opt out guidance after their hospital stay should they wish to opt out at a later date.

Individuals who have opted out of the use of their data for research either via the national data opt out system, or who have requested that their data not be included in CHARMER WP3 via ward staff will not have their data entered into the study database by site staff. The deadline for organisations to comply with the national data opt out is 31 August 2022. The timing of the active study window for CHARMER WP3 is after this date. We will therefore use the national data opt out processes at each site to ensure that dissenting patients' rights are respected.

The leaflet includes contact details of the study team at each site and the site Principal Investigator’s contact details to enable patients to request that their data not be included should they wish to opt out of this study specifically rather than use the national data opt out. Participating sites will also be asked to include study information in the body of the discharge letter according to local discharge processes and templates to ensure that patients are made aware of the study taking place and the importance of the enclosed leaflet.

The CAG would like confirmation that, however someone has dissented, this dissent will be respected.

Patient and Public Involvement and Engagement

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

The use of patient identifiable data for the purposes of accurate data linkage has also been co-designed with the three PPI representatives within the CHARMER feasibility study team at study management group meetings; more widely with the whole programme PPI team (5 members), with the NIHR CRN and 4 prospective hospitals. These discussions have included the study design, data linkage process, data management, anonymisation once linkage has taken place and participating hospital site communication strategies.

Information about the use of identifiable data without consent has also been shared via the study Twitter account @CHARMER_study https://twitter.com/CHARMER_Study?ref_src=twsrc%5Egoogle%7Ctwcamp%5Eserp%7Ctwgr%5Eauthor between 22/02/222 and 29/03/2022, including the use of video animation https://www.youtube.com/watch?v=8T2Qus06xJk

The CHARMER PPI team members are all aged over 60 and represent a diverse range of experiences, both as patients and carers; with personal experience of managing complex medication regimes, multi morbidity and navigating barriers to care and participation such as language. PPI members were required to have knowledge or experience of issues relevant to the CHARMER programme. They have each provided further details on their backgrounds and interest in CHARMER on the programme website: https://charmerstudy.org/ppi-team/

Throughout CHARMER, the research team have engaged with Third Sector and NHS groups championing patients and older people. As part of the programme's ongoing communication and dissemination strategy, they have reached out to The Alzheimer's Society, Mind, Versus Arthritis, Age UK and the Patient's Association informing them of the programme's aims and seeking ongoing engagement. They have also met with Prof Alf Collins, NHS England's Clinical Director and expert in patient engagement.

Alongside the development of this infrastructure to support ongoing PPI work throughout the programme, the CHARMER embedded PPI group representatives have been directly consulted on unconsented data access. The programme grant review process, which included PPI representation, deemed it absolutely essential that a minimum dataset be captured for all patients exposed to the intervention and those receiving standard care. The application for section 251 support where patients cannot be approached for informed consent is supported by our PPI group as a suitable method to achieve this; that respects the legal and ethical rights of patients.

The PPI group have reviewed the protocol and proposals, and had the opportunity in regular meetings to ask questions. Discussions have included definitions of anonymisation and pseudonymisation, data transfer processes within the NHS and via N3 connections, the importance of identifiers for accurate data linkage and opt out mechanisms.

The CHARMER PPI team recently distilled their core involvement in the programme of research in an international blog post for the Canadian Deprescribing Network, available here: Guest Blog Post #15: Patient and Public Involvement in Deprescribing Research - Deprescribing.org

A process evaluation is part of the feasibility study trial design and the numbers of patients who consent, refuse consent or opt out via the mechanisms in place will be captured, alongside views of patients and family members on their experience of the trial through in-depth interviews with 24 patients and consultees (6 per participating site). These will inform the development of the definitive trial protocol. Other planned activities include a workshop in autumn 2022 in partnership with the NIHR CRN Ageing Speciality, which will include patients and be a valuable opportunity to get feedback on our proposals for data collection, including use of identifiable information without consent. In November 2022 Prof Bhattacharya will be presenting the programme achievements to date and our plans for the definitive trial in 2023 to the British Geriatrics Society.

The CAG were extremely impressed with the level of PPI conducted, saying that, although numbers were small, the relevant lived experience of the group made the feedback invaluable.

Exit strategy

Once NHS Digital has linked the data, support can end, since an anonymised dataset is provided back to the Norwich Clinical Trials Unit.

The CAG was satisfied with the exit strategy.

Quality of application

The CAG would like to congratulate and thank the applicants on a well-researched and well thought out application.

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 07 April 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 review for **Northern Care Alliance NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 May 2022)

The NHS Digital **20/21** DSPT review for **London North West Healthcare NHS Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 May 2022)

The NHS Digital **20/21** DSPT review for **Norfolk and Norwich University Hospitals NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 May 2022)

The NHS Digital **20/21** DSPT review for **Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 May 2022)

The NHS Digital **20/21** DSPT review for **University of Leicester** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 May 2022)

The NHS Digital **20/21** DSPT review for **NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 May 2022)

3. Please confirm that however someone dissents, this dissent will be respected.

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

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

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

Public interest

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

The CAG were agreed that this was an important study which was clearly in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

The applicant reasons that the large sample sizes means that consent is not practicable. Applicants wish to maximise the representativeness of the project sample to a general psychiatric/ clinical population, and to minimise the risk of re-dentification through small cell sizes, as there may be a number of potentially rare mental health difficulties. Therefore the applicants wish to link the maximum possible number of cases. Additionally, seeking individual consent for study participation on this scale significantly raises the risk of incurring response bias. This bias threatens the utility of a study in addressing the proposed aims. Responders versus non-responders are often likely to be significantly different on a range of variables of interest, including the presence of mental health difficulties. Of the proportion of service users that do not respond to requests for consent, service users with the most complex needs are most likely to be in this group. The CAG accepted the justifications provided that consent is not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage, and the dataset is being effectively anonymised as early as possible. The Members accepted that the use of confidential patient information for the purposes of linkage did not appear to have a practicable alternative.

'Patient Notification' and mechanism for managing dissent

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

The applicant has provided the generic KCH and SLaM Privacy Notices and generic CRIS leaflets which describe the work of CRIS (one for adults, and one for children), as well as providing information about the CRIS project as a whole and how patients could dissent from the inclusion of their data from use in CRIS.

The applicant has provided a CRIS Communications plan which includes information on all comms for CRIS – including presentations to patient groups, etc. and CRIS linkages (including this study once linkage is complete) do form a part of that comms plan. It is stated in the application that SLaM patients will have received information on the SLaM CRIS mental health records and how they are used in research.

Bridging the Gap will also be publicised on social media, and on pages on the KCH website and the CRIS website. A local opt out addition for this renal study will be included, and website text has been provided.

The applicant has indicated that physical posters for the relevant clinical areas of KCH are planned, but this document has not been provided.

The National Data Opt-out is applied prior to sending Renalware data to CDLS. The National Data Opt-out and local opt out is applied by the SLaM CDLS team for individuals in the CRIS dataset prior to linking with Renalware data.

The CAG noted that in broad terms, the methodology of notification is sufficient, in that there will be a website text on both KCH and CRIS website offering an opt out option, and both study specific and national data opt out will apply. However there are elements of the methodology that were queried by the Members, alongside the content of the notifications. Firstly, it appears the linkages only appear in CRIS communications after they are undertaken, so this provides no opportunity to opt out, as this will not be possible after the linkage. The Members noted that both the KCH website notification, and the CRIS notifications regarding this linkage should be displayed on the websites in good time prior to extraction, to allow people time to object if they wish.

The Committee noted that although the applicant has confirmed a poster will be used, the CAG have not seen this document to review. This poster will need to be provided prior to support being provided, and the Members agreed it was important to have a physical poster available as well as online information.

Regarding the content of the website notifications, the members noted that these are currently not user friendly, and will need to be revised. The CAG felt that in general it should be written in plainer language, for a lay audience, and remove any acronyms that are not explained. Members noted that the language surrounding who the cohort is needs to be more specific – the terminology ‘severe mental health difficulties’ seemed to be used interchangeably with ‘mental health difficulties’ and it therefore might be unclear to patients who the study involves and whether or not it applies to them.

The wording of the website notification also needs to be altered to ensure patients are not misled. The current format states that the CDLS ‘has’ linked, which suggests this linkage has already been undertaken. This should be changed to ensure that actions ‘will be’ undertaken rather than ‘have already been done’.

Additionally, the Committee noted that the opt out option provided was only an email address, and that this should also include a phone number and if possible a postal address.

Patient and Public Involvement and Engagement

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

Three meetings with an expert patient panel of ESKD patients with a history of mental health difficulties have been held, to inform the study design. There were four patients on the panel, each of them had a diagnosis of end stage kidney disease and a mental health difficulty. The meetings took place virtually, over two hours. At each meeting, a 20 minute long presentation on the study was given by the researchers. The panel reported that it was acceptable to provide the CDLS with identifying information, given the potential benefits of the research in terms of improving care for individuals with CKD and mental health difficulties.

Applicants have also involved King's Health Partners Mind Body Programme PPI group, and plan to work with Kidney Research UK, and Kidney Care UK.

The Members noted that although the patient and public involvement work currently undertaken did appear to be good, it was noted that only individuals with both kidney disease and mental heath difficulties were involved. The CAG felt that as the Renalware database would likely contain mostly patients with only kidney disease, and no mental health difficulties, that this group should also be approached, as their confidential patient information would be accessed as part of this application.

The CAG also noted that although stating that King's Health Partners Mind Body Programme PPI group have been involved, it is not clear how, and it appears that Kidney Research UK, and Kidney Care UK have not yet been involved, and again, the CAG wished to see some feedback as to what was undertaken with King's Health Partners Mind Body Programme PPI group, and how the charities will be involved in the future.

Exit strategy

Only de-identified data will be retained following the linkage and validation, which will be completed within six months. All patient identifiers will be destroyed once the linkage and validation is complete. Once this is done 'S251' will no longer be required. The CAG were content with this exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further

information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

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

Request for further information

1. Please 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.

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

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.

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.

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.

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

Specific conditions of support (provisional)

The following sets out the specific conditions of support.

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

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

The NHS Digital **20/21** DSPT 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)

5. Minutes of the meeting held on 24 March 2022

The minutes of the meeting held on 24th March were not reviewed as an outcome is pending.

6. Any other business

The Members discussed the SDDR pilot application process with the CAT.

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

Minutes signed off as accurate by correspondence from:-

Signed – Officers of CAG	Date
Dr Murat Soncul, CAG Alternate Vice Chair	*08 June 2022*
Dr William Bernal, CAG Alternate Vice Chair	*08 June 2022*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, Confidentiality Advisor	*24 May 2022*