Minutes of the meeting of the Confidentiality Advisory Group

06 October 2022 via Zoom

Present:

Name	Role
Dr Murat Soncul	Alternate Vice Chair
Professor William Bernal	Alternate Vice Chair
Dr Malcolm Booth	CAG Member
Mr David Evans	CAG Member
Dr Katie Harron	CAG Member
Dr Pauline Lyseight-Jones	CAG Member
Ms Rose Payne	CAG Member
Professor Sara Randall	CAG Member
Mr Dan Roulstone	CAG Member
Mr Umar Sabat	CAG Member

Also, in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr Will Lyse	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor
Paul Mouncey	Head of Research (present for discussion of item 3a only)
David Harrison	Head Statistician and SIRO (present for discussion of item 3a only)
Andrew Fleming	National Clinical Audit Manager (present for discussion of item 3a only)
Kate Evans	Observer – HRA Product and Delivery Manager

1. Introduction, apologies, and declarations of interest

CAG member Mr Anthony Kane gave apologies.

The following conflicts of interest were declared.

1. COI – CAG Member Professor William Bernal (AVC) had a conflict of interest with item 3a – as he is undertaking research with ICNARC, and therefore did not participate in the development of the recommendation provided by the CAG.

2. COI – CAG Member Professor William Bernal (AVC) had a conflict of interest with item 4c – as he is a close colleague of an applicant, and therefore did not participate in the development of the recommendation provided by the CAG.

2. Support decisions

Secretary of State for Health & Social Care Decisions

No non-research applications were discussed at the **08 September** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **08 September 2022** meeting applications.

Minutes:

The minutes of the following meetings have been ratified and published on the website:

- Published July Sub-committee
- Published 14 July, 25 August Full
- Published 19 August, 02 September Precedent set

3. Consideration Items - National Data Opt out exemption applications:

a. PIAG 2-10 (f) 2005 (CMP) - ICNARC Case mix programme (CMP)

Scope of NDO exemption request

This is a request to defer the national data opt out for PIAG 2-10 (f) 2005, non-research application. The Intensive Care National Audit and Research Centre (ICNARC) case mix programme application has been supported since 2005, and is run by The Intensive Care National Audit and Research Centre.

Support is in place for clinical teams to provide ICNARC with confidential patient information, for the purposes of assessing quality in the organisation and delivery of critical care. A previous amendment to the Case Mix Programme supports linking to death registration data from NHS Digital for routine analysis and reporting in the

audit. This is not currently happening, although applicants are looking to introduce it into routine processing in the future.

The applicants submitted this request alongside a second non-research application, ECC 2-06 (n) 2009 (which is provided as a separate outcome letter). This outcome letter relates only to the non-research activities undertaken under CAG reference PIAG 2-10 (f) 2005.

Confidentiality Advisory Group advice

As part of the request, the applicant provided two core reasons why application of the NDO would impact the running of ICNARC CMP.

1. Patient safety – loss of data will reduce the ability to detect signals of concern to patient safety, and reduce the ability to monitor individual Trust performance

2. Introduction of bias – there are indications that the application of the National Data Opt Out is not random so impacts the integrity of the data

1. Deferral rationale: patient safety

The paper set out a strong argument detailing the potential impacts on patient safety. This included how data is used to monitor performance. Patients do not choose to become critically ill, and, consequently, they do not choose where they are treated. It is therefore imperative that the NHS monitors and ensures a high standard of critical care and outcomes across all providers.

The ICNARC CMP is responsible for benchmarking patient outcomes, and the identification of critical care units which are 'outliers' for risk-adjusted mortality and other important quality indicators. This process depends on the completeness of data from each hospital. Any casemix model will be sensitive to incomplete data, and geographical variation in the impact of the NDO means that hospitals in some areas will appear to perform better or less well, simply because of the extent of missing data that will arise with the application of the NDO. Some hospitals will therefore be falsely reassured of the quality of care they are providing, whereas patients and staff in other hospitals may be misidentified as a concern for the same reason. The applicant reasons there is also wasted time and money spent, and unnecessary negative emotional impacts for the staff involved, if units are incorrectly identified as poor performing.

The applicants provided a simulation to model how long it would take to identify a poor performing unit with a 10% increased risk of death, if the National Data opt out were applied. Using a rate of 5% of patients opted out resulted in an average delay of two months in identifying the unit as an outlier. If the rate of opt outs increased to 10%, the resulting delay was six months, on average. For a smaller critical care unit with a throughput of 200 patients per year (the throughput for one in 20 critical care units in the Case Mix Programme), these delays increase to six months and seventeen months, respectively. This potential delay in identifying a 10% increased

risk of death is a risk to patient safety, and would cause avoidable deaths in individuals who are treated in a critical care unit, and would affect all patients, including those who have not opted out via the NDO.

Members were supportive of exempting the NDO regarding the non-research elements of the CMP, due to the strong patient safety impact, commenting that the justification was well stated.

2.Deferral rationale: Introduction of bias

The paper focused on concern around the non-random nature of existing objections. The paper indicated that excluding patients that have registered against the NDO will introduce a biased sampling frame due to non-random opt-out patterns. The data opt out figures from NHS digital show that as of 1 April 2022, 5.4% of the population registered with a GP practice had registered a national data opt-out; however, across individual Clinical Commissioning Groups, this ranged from 2.2% to 11.1%. The applicant stated that case ascertainment was 100%. Therefore, Members were convinced that the NDO would cause an additional significant amount of bias.

Members were supportive of exempting the NDO regarding the non-research elements of the audit, due to the impact of bias.

Informing the patient population

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

The applicant stated that the current CMP specific opt out rate is currently extremely low. CAG discussed with the applicant regarding any concerns that this may suddenly increase, if exempted from the NDO. The applicant responded that they did not feel this is likely to be an issue, as patient and public involvement undertaken indicate that patients are likely to agree that the exemption of the NDO application for this use of data was appropriate, and therefore the applicant felt confident that local opt out rates would not rise as a result.

The applicant provided a draft edited leaflet and poster, regarding informing the population that the NDO would not be applied, and a communications plan.

The CAG were content with the communication plan provided. Members were broadly content with the notification materials provided, noting that these had been reviewed by a patient and public involvement group.

In addition, despite the applicant confirming a local opt out would continue to apply, the Members did not find it easy to work out how a patient would do so from the

information provided in the draft poster. The applicant is required to update the poster accordingly, to make it clear how a patient could opt out if they wished.

Patient and Public Involvement

The applicant noted that with regards to patient and public involvement, ICNARC held a dedicated online patient and public engagement session in August 2022. This was organised with ICUsteps (www.icusteps.org), an intensive care patient support charity. 8 people attended, and the NDO exemption was discussed. All were very supportive of this application for exemption. The CAG felt that this discussion was sufficient to recommend support for the exemption, however the Members felt that they would like to see evidence of further patient and public involvement and engagement, with more than 8 individuals, that further supported the non-application of the National Data Opt-Out, to ensure the patient and public involvement undertaken is proportionate to the application. The CAG asked that feedback from this was provided at annual review. The applicant agreed in the discussion that they are trying to do more already, and acknowledged the difficulties of trying to find a non-biased patient group to discuss with, hence the initial discussions being undertaken with ICUsteps rather than going directly through ICNARC.

Confidentiality Advisory Group advice conclusion

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

Whilst a patient notification strategy and draft notification materials were provided, the CAG felt that the applicant could improve the patient notification materials, and CAG should have oversight of these within one month.

Given that the applicants provided a notification strategy and draft documentation, CAG therefore recommended, in this specific instance, to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be conditionally approved.

Specific conditions of support

1. 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 PIAG 2-10 (f) 2005.

2. A local patient objection mechanism must continue to be used in relation to PIAG 2-10 (f) 2005.

3. Please provide an updated poster, which should make clear how a patient could opt out if they wished, within one month from the date of this letter.

4. Please provide evidence of further discussions with patients and the public, surrounding the non-application of the National Data Opt-Out, at annual review.

b. ECC 2-06(n)/2009- ICNARC National Cardiac Arrest Audit (NCAA)

Scope of NDO exemption request

This is a request to defer the national data opt out for ECC 2-06(n)/2009, non-research application. The Intensive Care National Audit and Research Centre (ICNARC) National Cardiac Arrest Audit application has been supported since 2009, and is run by The Intensive Care National Audit and Research Centre.

Support is in place for clinical teams to provide ICNARC with confidential patient information, for the purposes of auditing in hospital cardiac arrests. The application does not undertake any linkages with any external data sources.

The applicants submitted this request alongside a second non-research application, PIAG 2-10 (f) 2005 (which is provided as a separate outcome letter). This outcome letter relates only to the non-research activities undertaken under CAG reference ECC 2-06(n)/2009.

Confidentiality Advisory Group advice

As part of the request, the applicant provided three core reasons why application of the NDO would impact the running of NCAA.

1. Patient safety – loss of data will reduce the ability to detect signals of concern to patient safety, and reduce the ability to monitor individual Trust performance

2. Introduction of bias – there are indications that the application of the National Data Opt Out is not random so impacts the integrity of the data

3. Technical impacts – the systems are not designed to apply the national data opt out on a direct entry system which will add workload to direct care teams to apply the national data opt out.

<u>1.Deferral rationale: patient safety</u>

The paper set out a strong argument detailing the potential impacts on patient safety. This included how data is used to monitor performance. Patients do not choose to have an in-hospital cardiac arrest, and, consequently, they do not choose

where they are treated. It is therefore imperative that the NHS monitors and ensures a high standard of post-cardiac arrest care and outcomes across all providers.

The ICNARC NCAA is responsible for benchmarking patient outcomes, and the identification of hospitals which are 'outliers' for risk-adjusted mortality and poorer care post in-hospital cardiac arrest. This process depends on the completeness of data from each hospital, and will be sensitive to incomplete data. Geographical variation in the impact of the NDO means that hospitals in some areas will appear to perform better or less well, simply because of the extent of missing data that will arise with the application of the NDO. Some hospitals will therefore be falsely reassured of the quality of care they are providing, whereas patients and staff in other hospitals may be misidentified as a concern for the same reason. The applicant reasons there is also wasted time and money spent, and unnecessary negative emotional impacts for the staff involved, if units are incorrectly identified as poor performing.

In the high-mortality setting of in-hospital cardiac arrest, a failure to identify poorer care would be likely to lead to potentially avoidable deaths. The applicants provided a simulation to model how long it would take to identify a poor performing Trust with a 20% reduction in survival rate, if the National Data opt out were applied. Using a rate of 5% of patients opted out resulted in an average delay of four months in identifying the unit as an outlier. If the rate of opt outs increased to 10%, the resulting delay was nine months, on average. For a Trust experiencing only 25 in hospital cardiac arrests per year (more than 10% of hospitals in the NCAA), these delays increase to ten months and twenty-five months, respectively. This potential delay in identifying a poorly performing Trust is a risk to patient safety, and would cause avoidable deaths in individuals who are treated in that Trust for in-hospital cardiac arrest, and would affect all patients, including those who have not opted out via the NDO.

Members were supportive of exempting the NDO regarding the non-research elements of the NCAA, due to the strong patient safety impact, commenting that the justification was well stated.

2.Deferral rationale: Introduction of bias

The paper focused on concern around the non-random nature of existing objections. The paper indicated that excluding patients that have registered against the NDO will introduce a biased sampling frame due to non-random opt-out patterns. The data opt out figures from NHS digital show that as of 1 April 2022, 5.4% of the population registered with a GP practice had registered a national data opt-out; however, across individual Clinical Commissioning Groups, this ranged from 2.2% to 11.1%. The applicant stated that case ascertainment was difficult to ascertain, but that this is likely to be higher than 85%. The NCAA also collects details about a very small pool of patients at each Trust, and therefore it is imperative that all possible cases are included. Therefore, Members were convinced that the NDO would cause an additional significant amount of bias.

Members were supportive of exempting the NDO regarding the non-research elements of the audit, due to the impact of bias.

3.Deferral rationale: technical impacts

The applicants indicated that applying the NDO would generate additional workload for hospital teams, because the way in which the data entry is designed is for the identifiers to be entered by the clinical team at the point of entry, which should be in as real time as possible. To apply the NDO, the clinicians are required to submit a file to the IG team at the Trust, in order for them to provide the team back with a list of those who have applied the NDO. This causes a time delay, and also as Trusts do not experience many in-hospital cardiac arrests per year, this means that NDO status will need to be checked on an individual patient basis before each record can be entered. If a trust has 75 in-hospital cardia arrests per year, this means the clinical team would have to individually liaise with the IG team 75 times. This would ultimately impact the NCAA's ability to deliver its remit in effectively.

Whilst the CAG noted the potential technical challenges articulated in the paper, it was also noted there had been a long lead-in period for implementation of the NDO. CAG understood that the NHS had been under considerable pressure during the last years due to COVID-19 and there has been necessary focus on other matters. However, Members were clear that practical difficulties around the NDO implementation would have to be very clear with evidence and not just statements of potential negative impact. Requests for deferral from the NDO from the CAG should be exceptional and based primarily on reasons other than that of system process issues. Members were therefore not persuaded that this specific reason provided sufficient reasonable justification to disapply the NDO.

Informing the patient population

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

The applicant stated that the current NCAA specific opt out rate is currently extremely low. CAG discussed with the applicant regarding any concerns that this may suddenly increase if exempted from the NDO. The applicant responded that they did not feel this is likely to be an issue, as from patient and public involvement undertaken, patients are likely to feel that this use of data was not a use that the NDO applied to and therefore the applicant felt confident that local opt out rates would not rise as a result.

The applicant provided a draft edited leaflet and poster, regarding informing the population that the NDO would not be applied, and a communications plan.

The CAG were content with the communication plan provided. Members were broadly content with the notification materials provided, noting that these had been reviewed by a patient and public involvement group.

Despite the applicant confirming a local opt out would continue to apply, the Members did not find it easy to work out how a patient would do so from the information provided in the draft poster. The applicant is required to update the poster accordingly, to make it clear how a patient could opt out if they wished.

Patient and Public Involvement

The applicant noted that with regards to patient and public involvement, ICNARC held a dedicated online patient and public engagement session in August 2022. This was organised with ICUsteps (www.icusteps.org), an intensive care patient support charity. 8 people attended, and the NDO exemption was discussed. All were very supportive of this application for exemption. The CAG felt that this discussion was sufficient to recommend support for the exemption, however the Members felt that they would like to see evidence of further patient and public involvement and engagement, with more than 8 individuals, that further supported the non-application of the National Data Opt-Out, to ensure the patient and public involvement undertaken is proportionate to the application. The CAG asked that feedback from this was provided at annual review. The applicant agreed in the discussion that they are trying to do more already, and acknowledged the difficulties of trying to find a non-biased patient group to discuss with, hence the initial discussions being undertaken with ICUsteps rather than going directly through ICNARC.

Confidentiality Advisory Group advice conclusion

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

Whilst a patient notification strategy and draft notification materials were provided, the CAG felt that the applicant could improve the patient notification materials, and CAG should have oversight of these within one month.

Given that the applicants provided a notification strategy and draft documentation, CAG therefore recommended, in this specific instance, to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be conditionally approved.

Specific conditions of support

1. 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 2-06(n)/2009.

2. A local patient objection mechanism must continue to be used in relation to ECC 2-06(n)/2009.

3. Please provide an updated poster, which should make clear how a patient could opt out if they wished, within one month from the date of this letter.

4. Please provide evidence of further discussions with patients and the public, surrounding the non-application of the National Data Opt-Out, at annual review.

4. New Applications

a. 22/CAG/0137 - West Yorkshire ICB S251 non-research

Purpose of application

This non-research application from the West Yorkshire Integrated Care Board (ICB) set out the purpose of using patient data to enable a whole system approach to supporting the reduction of health inequalities and improvement of efficiency of the health and care offered.

The main aims of the Population Health Management (PHM) solution will be to improve the mental and physical health outcomes and wellbeing of patients, the reduction of health inequalities, reducing the re-occurrence of ill-health and use of Artificial Intelligence to risk stratify and target individual and communities at risk of deteriorating health.

The North of England Commissioning Support Unit (NECS) will extract primary care data from all GP practices in the West Yorkshire area. Once the datasets are received by NECS, a common pseudonym will be applied. Data from the Commissioning Datasets, held by NHS Digital, will be sent from NHS Digital to NECS, using the same common pseudonym to allow NECS to link the datasets. The pseudonymised dataset will then be stored at a data warehouse within West Yorkshire ICB for analysis. Pseudonymised data will also flow back to the GP practices, this data will be limited to the practice's own patients. Patient NHS numbers will be held by NECS for re-identification purposes only

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	All active patients in the West Yorkshire area. The applicants anticipate that 2.6 million patients will be included.
Data sources	1. GP practice data 2. Commissioning Datasets held by NHS Digital
Identifiers required for linkage purposes	1. NHS Number
Identifiers required for analysis purposes	1. NHS Number The applicants confirmed that the NHS Number would not be used for analysis but would be retained for re-identification purposes.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

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

Scope

The application stated that NHS Digital will carry out linkage of the GP practice data to Commissioning Datasets held by NHS Digital. Members asked that a complete list of the datasets held by NHS Digital that would be linked to was provided.

Practicable alternatives

The 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**

The CAG requested clarification on the reidentification process, including how this would be undertaken and in what circumstances patients who need to be re-identified.

The CAG also requested clarity on where the pseudonymisation key would be held and who would be able to access it.

- **Feasibility of consent**

The applicants stated that the population of West Yorkshire is 2.6 million and therefore it would not be feasible to seek consent from patients.

The CAG was content with the justification, that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

CAG was content that use of anonymised data 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.

An information flyer was provided. This explained that patients de-identified data would be used, and that confidential patient information would be processed. The flyer contained a QR code, directing to online information. The flyer also included an

alternative option to using the QR code if a hard copy of the flyer was not available or if patients could not access the QR code.

Patients wishing to opt out of the PHM project will be asked to contact their relevant GP practice. If a patient contacts the ICB directly (using the listed contact details on the flyer), then the patient will either be directed to their practice or details will be taken and forwarded to the relevant practice to action. The GP practice will then be responsible for ensuring that the project specific opt-out read code is applied to the patients record. This code will then be used to ensure the patient is excluded from the project. NHS Digital will apply the National Data Opt-Out.

The CAG requested further details on the training that the staff in participating GP surgeries would receive around application of the National Data Opt-Out and the project-specific opt-out to ensure that they were well equipped to deal with any queries or other additional workload resulting from the application. Members also asked if the GP surgeries would be given any guidance or information around the National Data Opt-Out and project specific opt-out.

CAG reviewed the patient notification materials and felt that the content was not lay friendly, for example many sentences were lengthy and hard to understand. CAG requested that the patient notification materials were revised to use language more accessible to the patient population.

In addition, the patient notification materials should have specific additions to confirm that identifiable information is being used, and the differences between a local opt out and the National Data Opt-Out.

The ‘Communication Strategy’ was noted as being too instructive. The CAG noted that, although the table on page 3 was informative, the wording used did not promote engagement to help capture the participants opinion. Therefore, the CAG requested for the wording of the table to be amended to encourage back and forth communication between the applicant and participants.

Patient and Public Involvement and Engagement

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

The applicants plan to present the application to the Public Patient Experience Committee PPEC, a patient experience committee that provides advice on how to approach speaking with the public. The application will also be discussed with the Digital Patient Advisory Group, a digital patient group that supports the systems digital agenda. Both above groups include patient representatives from various backgrounds and from across all areas of the district.

Little patient and public involvement activity had been undertaken, which the applicants acknowledged. The applicants provided an engagement plan

The CAG was content with the plans to undertake Patient and Public involvement within the study.

Exit strategy

The applicants are initially seeking support under s251 for 36 months, as they anticipate the introduction of statutory laws to allow Health and Care organisations to process confidential information for population health management purposes. An extension to s251 support will be sought if support is required for longer than the initial 36-month period.

The CAG was content with the exit strategy proposed.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Please clarify the data sets being used from NHS Digital.

2. Please clarify how the reidentification process works.

3. Please clarify who is holding the key for pseudonymisation and how and when the key will be used.

4. Please clarify what training was given to the GP surgeries to help equip them to deal with the high volumes of work from this study.

5. Please clarify the amount of guidance and information GP surgeries will be given, regarding opt-out.

6. The patient notification materials need to be revised as follows:

a. The materials need to be revised into lay-friendly language.
b. The materials should be reviewed during patient and public involvement.
c. The patient notification materials need to explain that identifiable data will be processed during the application.
d. The patient notification materials need to explain the National Data Opt-Out and the project-specific opt-out.

7. The 'Communication Strategy' is noted as too instructive. Therefore, please amend the language used, in the table, on page 3, to encourage back and forth engagement between the applicant and participants.

Specific conditions of support (provisional)

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

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

   NHS Digital 2021/22 DSPT review for **NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (11/10/2022)

   Pending:

   NHS Digital 2021/22 DSPT reviews for **West Yorkshire Integrated Care Board andThe North of England Commissioning Support Unit (NECS)** were confirmed as 'Pending' on the NHS Digital DSPT Tracker (11/10/2022)

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

b. 22/CAG/0140- Exploring the effectiveness and cost-effectiveness of text-message reminders and telephone patient navigation to improve the uptake of faecal immunochemical test screening among non-responders in London.

Purpose of application

This application from University College London sets out the purpose of medical research that seeks to test the effectiveness of text message reminders in improving patient take up of bowel cancer screening.

Bowel cancer is a leading cause of cancer-related mortality in England. Previous randomised controlled trials have shown that faecal occult blood test screening every two years can improve bowel cancer outcomes by detecting cases earlier. NHS England commenced a national bowel cancer screening programme (BCSP) in 2006. Uptake of this screening has been low. In June 2019, the English BCSP changed to a new test, the faecal immunochemical test (FIT), which increased uptake by around 7%. However, an important issue that has not yet been addressed is lower uptake of screening in London. Several interventions, such as sending pre-invitation letters, GP endorsement and postal reminders have ben trialled. Text message reminders and patient navigation (PN) have not yet been implemented, although a recent service evaluation in Southeast London showed that a combination of text message reminders and PN facilitated uptake increased take up of breast screening. The applicants are seeking to determine whether these interventions can be used to improve uptake of bowel cancer screening.

The NHS Bowel Cancer Screening invitation process will continue, unaffected by this study. Only those who do not participate within 13 weeks of invitation will be included in the study. During the pre-trial period, at week 0, pre-invitation letters will be sent to the potentially eligible participants. At week 1, the screening kit will be dispatched. At week 5, a reminder letter will be sent to the bowel non-responders. At week 13, it will be the end of screening episode, and non-responders will be identified and randomised at this point. NHS Digital will identify eligible patients from the NHS Continuing Health Care (CHC) Patient Level Data Set and National Bowel Cancer Screening Database. Patients who have registered a National Data Opt-Out will be removed. The data will be transferred to iPlato. iPlato will randomise patients into one of three groups, 1) no intervention ('usual care'), 2) a text-message reminder, which will be sent 13 weeks after invitation, followed by additional text-message reminders at 15, 17 and 19 weeks if there is no response, or 3) a text-message reminder, sent 13 weeks after invitation, followed by PN calls at 15, 17 and 19 weeks if there is no response. iPlato will use telephone numbers from the GP Clinical System at NHS Digital to send patient reminder texts and to undertake Patient Navigations calls. Patient navigation (PN) involves specially trained individuals giving tailored support to help patients overcome barriers. The end of data accrual period will be week 24, which will be 11 weeks after randomisation of the final randomised participants. The dataset will be returned to NHS Digital where outcomes and demographics will be added. The dataset will be anonymised and sent to UCL for analysis.

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

Confidential patient information requested

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

Cohort	Patients aged 60 – 74 years who have been routinely invited for bowel cancer screening, but not returned their test kit within 13 weeks of dispatch, during the trial period. Patients must also be registered with a GP located within the London Boroughs of Brent, Ealing, Lambeth, Lewisham, Redbridge or Barking and Dagenham. 2703 patients will be included.
Data sources	1. NHS Continuing Health Care (CHC), Patient Level Data Set and National Bowel Cancer Screening Database, held at NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number
Identifiers required for analysis purposes	1. Gender 2. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The CAG requested clarification on who sent the testing kits to the participants and how their addresses were obtained.

The CAG queried whether sending 4 text messages was excessive, however noted that this would be addressed separately by the Research Ethics Committee

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**

It was noted in the application that iPlato collected participant names and contact numbers. However, elsewhere stated, iPlato collected only NHS numbers and names. The CAG requested the applicant to address this discrepancy and clarify what data iPlato collected and for this to be made clear in the patient notification.

- **Feasibility of consent**

The applicants advised that consent was not practicable as they are seeking to assess the use of text message reminders and telephone patient navigation on uptake of bowel cancer screening. Seeking consent from patients would potentially mean that those patients who the study is aimed to help would not be included.

CAG was content with the justification provided by the applicant, that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

iPlato require access to confidential patient information in order to send text reminders and facilitate the PN calls.

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

'Patient Notification' and mechanism for managing dissent

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

with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants advised that a study webpage will be created. All patients are free to request their data not be used in this way at any time.

GP Practices will be provided with a patient notification poster for the research, which they can display in their practice / on their practice website. GPs will then need to notify iPlato, who will remove them from the study database. The patient notification materials had not been provided.

The National Data Opt-Out will be applied by NHS Digital.

The applicants clarified before the CAG meeting that, should patients request to opt out after becoming aware of their GP surgery's involvement, any data gathered will be disregarded and patients will be excluded from the analysis.

The CAG queried why participants couldn't contact iPlato directly regarding opt-out, instead of going through the GP.

CAG highlighted that no patient notification was submitted. The members requested these documents were provided for review.

Patient and Public Involvement and Engagement

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

The applicants advised that they had not testing the acceptability of processing confidential patient information without consent. The applicants cited that a previous study had demonstrated that a very small percentage (2.35%) had opted out of text message reminders for breast cancer screening, and that similar data are routinely shared with iPlato for the delivery of text message reminders for bowel and cervical screening.

Patient and Public Involvement is planned to take place following ethical approval. This activity will assist with intervention development and will determine the appropriate wording and timing of text messages and patient navigation. Two co-creation workshops will be held with a diverse range of screening eligible adults living within the target ICBs

This is planned to take place from October 2022 to January 2023, prior to GP recruitment.

The CAG requested to see, if any, feedback from the patient and public involvement group.

Exit strategy

NHS Digital will securely transfer confidential patient information for eligible adults to iPlato, who will collate the data in a study database. This database will be held for 13 weeks, the duration of the interventions phase. Data will then be transferred securely to NHS Digital, who will add participant demographics and outcome data, remove any confidential patient information and transfer the dataset to UCL's Data Safe Haven for analysis. The data will be deleted by iPlato following transfer.

The CAG was content with the exit strategy proposed.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Please clarify who sent the testing kits to the participants and how patient addresses were obtained.

2. Please clarify what data iPlato collects and for this to be made clear in the patient notification.

3. Please explain why participants couldn't contact iPlato directly regarding opt-out.

4. Please send the patient notification for CAG review.

5. The CAG request to see, if any, feedback from the Patient and Public Involvement groups.

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**

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 2021/22 DSPT reviews for **iPlato and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (11/10/2022)

C. 22/CAG/0141- Do patients with autoimmune hepatitis (AIH) have an excessive incidence of cardio- and cerebrovascular disease and is this related to corticosteroid treatment?

Purpose of application

This application from Sheffield Teaching Hospitals NHS Foundation Trust set out the purpose of medical research that seeks to investigate whether the rate of new hospital admissions and/or deaths is higher after a diagnosis of autoimmune hepatitis (AIH) than that in a general population cohort.

Autoimmune hepatitis (AIH) is a chronic inflammatory liver disease that affects about 11,000 people in the UK and is becoming more common. It can affect all populations and age groups, although most patients are female. Untreated, AIH is a serious and fatal disease. Drug treatments, such as steroids, are effective in improving outcomes, but have side effects such as weight gain, diabetes, and increases in blood pressure and fat levels in the blood and liver. Patients with other steroid treated conditions, such as rheumatoid arthritis, have a higher rate of vascular disease compared to the general population. The applicants seek to establish whether this is also true of patients with AIH and if there is a link to steroid therapy, in order to inform the development of newer, non-steroid treatments.

The three participating trusts, Sheffield Teaching Hospitals NHS Foundation Trust, Kings College Hospital NHS Foundation Trust and University Hospitals Birmingham will disclose confidential patient information, collected from the autoimmune hepatitis patient datasets they hold, to NHS Digital. NHS Digital will generate a control group, consisting of 10 controls per patient, matched to the patient group in age, sex and postcode (LSOA). NHS Digital will then link data for both the patients and controls with the HES Admitted Patient Care Dataset and ONS Mortality Dataset. The dataset will then be disclosed to the Chief Investigator at Sheffield Teaching Hospitals NHS Foundation Trust. The dataset for the case data will be pseudonymised, as the name, NHS number, date of birth, sex and post code will be replaced by the unique Study ID. The control dataset will be completely anonymous, with each patient identified only by their corresponding "case" Study ID.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over who were diagnosed with AIH between 1989 and 2021, and who are under the care of the Liver Units at Sheffield Teaching Hospitals, Kings College Hospital NHS Foundation Trust or University Hospitals Birmingham. In total there will be 8580 patients involved: 780 “cases” and 7800 “controls”.
Data sources	1. Electronic patient records at: a. Sheffield Teaching Hospitals NHS Foundation Trust b. Kings College Hospital NHS Foundation Trust c. University Hospitals Birmingham 2. The HES Admitted Patient Care Dataset and ONS Mortality Dataset, held by NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode – sector level
Identifiers required for analysis purposes	1. Date of death 2. Postcode – sector level 3. Gender 4. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

Scope

CAG noted that the application referred to the cohort as the general population. As a point of note, the CAG wished to make clear that this is incorrect as the cohort is specifically those individuals who have been admitted to hospital with the timeframe of the study. CAG advises this to ensure greater accuracy on this point moving forwards.

The CAG wondered whether the applicant trusted the reliability of ethnicity data as the classification had changed and is often left incomplete. The CAG queried whether this could cause a problem for when performing linkage.

The CAG requested clarification on whether the research team were using the full postcode for linkage and then obtaining the lower super output area.

Statistical Package for Social Sciences (SPSS)

The CAG requested for the use of SPSS to be only used on University resources (laptops/network) rather than personal devices.

Practicable alternatives

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

- **Feasibility of consent**

The applicants advised that consent was not feasible as a number of patients are deceased, and many are too ill or elderly to be approached for consent.

CAG was content with the justification, that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information needs to be disclosed from the participating NHS trusts to NHS Digital for linkage to the HES Admitted Patient Care Dataset and ONS Mortality Dataset.

The CAG noted "Hospital Episode Statistics (HES)" were referred to in the application as a government department. The CAG clarified that HES is a dataset held within NHS Digital.

The CAG requested clarification to where the key for pseudonymisation would be held and who would have access to 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.

The applicants provided a letter, which would be sent to all living patients with autoimmune hepatitis who are attending one of the three participating centres. This letter included a telephone and email address for patients to opt-out. The National Data Opt-Out will be applied.

Guidance from the Information Commissioner's Office was, should patients not respond to individual contact about a study, that this should be considered to be dissent. The CAG noted that this guidance was usually followed in CAG applications however, members determined that the notification letter sent to patients about this study would fall outside of this guidance, as long as it was made clear in the letter that patients would be included in the research unless they specifically requested that they were opted-out.

The CAG noted that it may not be possible for the applicants to obtain up to date addresses for all patients and asked that posters and/or leaflets were made available at appropriate hospital sites.

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 South Yorkshire AIH Patient Group was formed in 2011. The group has a five-person committee, which usually meets 1-2 times a year.

Feedback on the study protocol was sought from 5 patients, were approached by a member of the study team whilst attending their usual autoimmune hepatitis outpatient clinic, and permission sought to email the study documents to these patients to seek feedback. Feedback from those approached was supportive. Of the five patients consulted, 2 were male and 3 were female. The age range was from 52-75 years. One of the patients, whose feedback is attached, is the Head of the South Yorkshire AIH Patient Group. The remainder of the patients are not members of this group.

The applicants noted that they are willing to repeat this process in a more explicit and focused way, if needed, by sending a questionnaire to a larger number of patients.

The CAG noted that patient and public involvement was too small and that it should include patients and the public from different areas of the country, to reflect the study population.

The possibility of holding patient and public involvement meetings more frequently than annually should be explored. If this was not feasible, provide justification as to why.

Exit strategy

Only anonymised data for the control dataset will be disclosed from NHS Digital to Sheffield Teaching Hospitals NHS Foundation Trust. For the case cohort, this dataset will be pseudonymised, as the name, NHS number, date of birth, sex and post code will be replaced by the unique Study ID.

The CAG was content with the proposed exit strategy.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. The term ‘general population’ should not be used to describe the study population in any of the patient-facing materials

2. The CAG query whether the applicant trusts the reliability of ethnicity data and whether it could cause a problem when performing linkage.

3. Provide clarification on whether the research team are using the full postcode for linkage and then obtaining the lower super output area.

4. The CAG requested for the use of SPSS to be only used on University resources (laptops/network) rather than personal devices.

5. The CAG wishes to inform the applicant that HES refers to a data set held within NHS Digital.

6. Please clarify where the key is going to be held for pseudonymisation.

7. Please include a sentence within the patient notification letter, explaining that the participant would not be opted out should they not to respond to the letter.

8. Notifications need to be displayed at hospital sites

9. The CAG note that the patient and public involvement group is too small and should include patients and the public from different areas of the country, to reflect the study population.

10. The possibility of holding patient and public involvement meetings more frequently than annually should be explored. If this is not feasible, please provide justification as to why.

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**

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 2021/22 DSPT reviews for **Sheffield Teaching Hospitals NHS Foundation Trust, University Hospitals Birmingham NHS Foundation Trust and NHS Digital** were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (11/10/2022)

Pending:

The NHS Digital 2021/22 DSPT review for organisation **Kings College Hospital NHS Foundation Trust** was confirmed as ‘Pending’ on the NHS Digital DSPT Tracker (11/10/2022)

d. 22/CAG/0144- Randomised Evaluation of SOdium dialysate Levels on Vascular Events

Purpose of application

This application from University College London set out the purpose of medical research that seeks to determine the optimal default dialysis sodium concentration, and the impact of higher or lower dialysate sodium concentration on cardiovascular events and death in patients with kidney failure who are receiving haemodialysis.

Over 24,500 people in the UK are receiving haemodialysis to treat kidney failure. Those receiving haemodialysis have a mortality rate 10 to 100 times higher than in the general population and most deaths are due to cardiovascular disease. A main contributor to this is retention of sodium and fluid, which causes thickening of the heart muscle, wide changes in weight between dialysis sessions and vascular disease. Dialysate is a saline solution exposed to blood during the dialysis session. Most units use a default dialysate sodium prescription, meaning that all patients treated at the unit receive the same concentration, unless specifically altered by the responsible physician. There is no consensus as to the optimal dialysate sodium concentration.

100 dialysis centres will participate in the study. Confidential patient information will be transferred from participating sites to the UCL Data Safe Haven. The research team at University College London will collate the data and transfer confidential patient information to NHS Digital for linkage and to the UK Renal Registry for linkage. Linked datasets will be returned from NHS Digital and the UK Renal

Registry to the UCL Data Safe Haven. Linkages to NHS Digital and the UK Renal Registry will be undertaken on an annual basis.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over receiving haemodialysis for kidney failure. The applicants anticipate that 12,000 patients will be recruited in England.
Data sources	1. Confidential patient information from dialysis units at participating trusts 2. Hospital Episode Statistics Admitted Patient Care (HES APC), Emergency Care Data Set (ECDS), Civil Registrations (Deaths) data set, held by NHS Digital 3. The UK Renal Registry
Identifiers required for linkage purposes	1. NHS number 2. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. Gender

Confidentiality Advisory Group advice

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

Public interest

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

Scope

An inconsistency was noted regarding the number of patients within the UK. One section stated 20,000, whilst another noted 6,000 and then 12,000. The CAG requested for this to be clarified

Furthermore, the CAG requested clarity on which international countries were involved within the study.

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**

The CAG noted mention of a potential transfer of data outside of the UK and requested for this to be clarified.

- **Feasibility of consent**

The applicants advised that consent was not feasible as it was important to capture data for as many patients as possible in order to answer the research question.

The CAG queried whether it was feasible for consent to be taken, noting that only 60 patients would be consented at each participating unit. The CAG requested that the research team conduct statistical modelling to demonstrate that consent was not feasible

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to undertake the linkages to data held by NHS Digital and the UK Renal Registry. Confidential patient information is required to undertake the linkages to data held by NHS Digital and the UK Renal Registry.

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

‘Patient Notification’ and mechanism for managing dissent

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

Posters and patient information leaflets will be made available at participating dialysis centres. These advised patients to contact the dialysis staff or the research team for further information.

A patient’s dissent for RESOLVE data capture will be recorded in their medical records. A ‘Dissent Log’, will be maintained at each unit. This log will be shared with the trust research team, who will be trained and delegated to work on RESOLVE, to ensure that no patients listed have their data entered in REDCap or shared with UCL CCTU. Guidance text will also be added on REDCap to remind delegated site team members not to add data from those patients included on the Dissent Log. The National Data Opt-Out will be applied. Local research teams will ask their local trust information governance teams to identify and remove patients listed as having opted out. NHS Digital will also apply the National Data Opt-Out.

To reflect the population of locations covered, the CAG queried whether the patient notification could be translated into other languages.

The CAG asked that the patient notification was revised to provide further details about how patients could opt-out and to provide the relevant contact information.

Information about how information would be shared with Australia also needed to be included.

Patient and Public Involvement and Engagement

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

A Patient Advisory Group (PAG) has been created for the RESOLVE trial. The PAG is comprised of those with experience of kidney failure and dialysis. A face-to-face PAG meeting took place during the first stage of the funding application process. At stage 2, the PAG were re-approached to consult on the study design, and they fully endorsed the need to collect identifiable data in order to facilitate the extraction of study outcomes from the UK Renal Registry and NHS Digital.

The Patient Advisory Group highlighted the need for a pathway for patients to be able to opt-out of their data being used for the purposes of the study. They suggested that that availability of this “opt out” option should be specified in the study information made available to the patients at participating dialysis units. A process will be put in place at participating units for those patients who opt-out of RESOLVE data collection.

The CAG requested information on the patient and public involvements group’s feedback regarding the use of confidential patient information without consent.

Exit strategy

The data linkages to the UKRenal Registry and NHS Digital will be repeated on an annual basis. Following the completion of analysis, the confidential patient information will be deleted

The CAG was content with the exit strategy proposed.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Please provide clarity on which international countries are involved in this study as well as the number of patients within the United Kingdom and internationally.

2. Please provide clarity on the data flows and how the data would be sent out of the country.

3. Statistical modelling needs to be undertaken to demonstrate the impact the seeking consent would have on the study, to evidence that consent is not feasible.

4. The patient notification materials need to be revised as follows:

    a. Specific details on how patients may opt-out need to be given, including the relevant contact details.

    b. The potential transfer of data outside the UK should be specified.

c. The possibility of making patient notification materials available in languages other than English needs to be explored.

5. Provide feedback on from the patient and public involvement group on the use of confidential patient information without consent.

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**

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 2021/22 DSPT reviews for **University College London, NHS Digital and The Renal Association** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (11/10/2022)

Pending:

The NHS Digital 2021/22 DSPT review for organisation **Dialysis centres at participating trusts** - 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.

5. Any other business

- Professor William Bernal (AVC) noted that the Confidential Advisory Group were recruiting members and highlighted that there had been substantial interest.

- The Chair noted a reminder to the CAG about the away day in December, prompting members to email CAT their dietary and travel requests.

- Kate Evans thanked the CAG for allowing her to observe.

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

Signed – Chair	Date
Dr Murat Soncul, CAG Alternate Vice-Chair *Professor William Bernal, CAG Alternate Vice-Chair*	*18 October 2022* *18 October 2022*

Signed – Confidentiality Advice Team	Date
Mr William Lyse, HRA Approvals Administrator	*02 November 2022*