Health Research Authority

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

March 2023

1. New Applications

a. 23/CAG/0004 - Using AI and Data Analysis to Better Predict Cardiovascular Disease

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Dr Martin Andrew	CAG member
Dr Pauline Lyseight-Jones	CAG member
Mrs Diana Robbins	CAG member
Ms Katy Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from Manchester Metropolitan University set out the purpose of medical research that seeks to identify digital signatures that relate to cardiovascular disease risk.

Prediction models are widely used in clinical practice. The NHS currently uses QRISK to quantify the risk of acute coronary syndromes (ACS) or stroke in primary care in patients not previously diagnosed with cardiovascular disease. QRISK demonstrates a good capacity to discriminate between those at a higher or lower risk, but it should be possible to improve performance by using computer aided analysis of patient data to develop understanding of the interaction between different indicators of risk and how they cluster in patients that suffer heart attacks.

Patients will be identified from records at Salford Royal Infirmary, part of the Northern Care Alliance NHS Foundation Trust, and Wythenshawe Hospital and Manchester Royal Infirmary, part of Manchester University NHS Foundation Trust. The data will be collated into a single dataset by research staff at Salford Royal Infirmary. Once linked, the dataset will be anonymised and uploaded to the Northern Care Alliance NHS Foundation Trust.

The anonymised dataset will be analysed by staff at Northern Care Alliance NHS Foundation Trust and Manchester Metropolitan University.

A separate file linking the study participant study number and NHS number will be securely retained within the NCA NHS system. The need to retain this file will be reviewed at least annually by the study team and will be deleted at the end of the study, or at the latest 5 years from ethical approval, unless permission to extend the study is obtained.

A recommendation for class 1, 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	5000 patients. 2200 – 2500 patients aged 18 years and over who experienced ACS between 01 April 2015 – 31 March 2018 and were treated Manchester Royal Infirmary or Wythenshawe.

	2200 – 2500 validation cohort of patients treated between 01 April 2018 – 31 March 2021
Data sources	1. Primary healthcare data held in Salford integrated record 2. Secondary healthcare data held in electronic patient records at Northern Care Alliance NHS Foundation Trust and Manchester University NHS Foundation Trust 3. MINAP data from Wythenshawe and Manchester Royal Infirmary for patients that have a Salford postcode 4. BCIS data from Wythenshawe and Manchester Royal Infirmary for patients that have a Salford postcode
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. GP Registration 5. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – sector level 3. Gender 4. Ethnicity 5. Age at time of clinical event

Confidentiality Advisory Group advice

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

1. **Please provide the CAG with an amended data flow diagram which clearly explains where the confidential patient information will be handled and where it has come from and where it is being processed.**

The applicants provided a revised data flow diagram which clarified where the information was sourced form, who is processed the data under s251 and the point where confidential patient information is deleted.

2. **Please re-submit a revised patient leaflet and poster, providing clarity on the primary outcomes of the study, as well as information on the length of data retention and exit strategy.**

The applicant provided a revised patient information sheet.

3. **Please clarify where the patient notification will be displayed.**

The applicant advised that the patient leaflet would be displayed at Salford Royal Cardiology Department. It would also be emailed to GP practices to be displayed within primary care settings, and sent to the 'Salford Heart Group', a CCG-facilitated patient support group. The previous versions of the patient information sheet have been circulated to the heart disease patients with 'Research for the Future' for feedback, so this study has already been highlighted to relevant patient groups.

4. **Further patient and public involvement need to be undertaken and the discussions need to include the use of confidential patient information without consent as proposed in the application.**

The applicants had engaged with heart disease patients within the 'Research for the Future' group, using v2 of the patient information sheet. Those consulted were content that confidential information was used in the study, with the proviso that all identifiable data was removed prior to any analysis of the data.

5. **Provide clarification on the proposed exit strategy and how long the research team will retain the confidential patient information.**

The requirement to retain the files for analysis will be reviewed at least annually. The data will be deleted within 5 years of commencing the study, unless an extension is agreed with appropriate ethical/CAG support. This will be sought in the eventuality that the data could be combined with larger national efforts to understand the drivers of cardiovascular disease, or to allow the follow up period to be extended, without having to re-extract all the patient history already complied within the study analysis file.

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. The CAG asked that paragraph 4 of the patient information leaflet was revised to describe CAG as an "independent group of experts and lay people", rather than as a government group. The revised patient information leaflet is to be provided within 30 days of the issuing of this letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed (REC Favourable Opinion issued 02 November 2022)**

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

The NHS Digital **21/22** DSPT reviews **DSPT** for **Northern Care Alliance NHS Foundation Trust** and **Manchester University NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 23 January 2023)

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.

Name	**Capacity**
Professor William Bernal	CAG Alternate Vice Chair
Ms Rose Payne	CAG member
Mr David Evans	CAG member
Mr Dan Roulstone	CAG member
Dr Katie Harron	CAG member

Ms Katy Cassidy	Confidentiality Advisor

Context

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

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

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

The applicant clarified that the Bowel Cancer Screening kits are sent to patients every other year. The Bowel Cancer Screening Programme has support under s251 to collect patients' names, dates of birth and addresses. For this study, text and telephone reminders will be sent to patients who do not return the screening kit within 13 weeks of the kit being sent out.

Participants will be able to request a new test kit, either by calling the Bowel Cancer Screening Programme freephone helpline or by being transferred through to the Bowel Cancer Screening Programme freephone helpline.

As stated above, the Bowel Cancer Screening Programme will handle all requests for a new bowel cancer screening kit directly with the patient. Any request for a new kit will be managed using data already held by the Bowel Cancer Screening Programme, and using pathways already in place.

The CAG noted the information provided and raised no further queries.

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

The applicants explained that iPLATO will receive a weekly list of names and NHS numbers, for individuals who have not taken part in bowel cancer screening within 13 weeks of kit distribution, from NHS Digital. iPLATO will then randomly allocate these individuals to one of three study groups, and access the telephone numbers(s) of relevant individuals from participating GP clinical systems. Telephone numbers will be accessed solely to call / text patients in the intervention groups. They will not be collected as data or stored in the study database.

The CAG noted the information provided and raised no further queries.

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

The applicants agreed that patients should be able to contact iPLATO directly to opt-out of the study. To enable this, the applicants included instructions on how to withdraw from the study within the text message reminder (received by all intervention participants), as well as the patient notification poster and website. The instructions for withdrawal on the patient notification poster and website include both the telephone number and email address for iPLATO. The text message reminder, meanwhile, includes the telephone number only.

The CAG noted the information provided and raised no further queries.

4. Please send the patient notification for CAG review.

The patient notification poster and a link to online information were provided.

The CAG reviewed the poster and website information and noted that neither explained how patients could opt-out. Members also noted that the text message contained a link to information about the National Data Opt-Out and queried whether a link to the relevant information on the HRA website would be more appropriate. The CAG also asked whether information about how to opt-out could be included with the kit when it is sent out.

The applicant advised that the website information would be revised to link to the HRA website.

The applicant noted that the link to the National Data Opt-Out was added to the text message at the request of the REC. The applicants also advised that patients would not be informed about their participation in the study until the end of the project, to ensure ecological validity and avoid demand characteristics, when they would receive a debrief letter. Those who had not seen the patient notification may be confused to receive a text message directing them to the HRA website. The applicants instead proposed adding a link to the HRA website to the debrief letter.

The CAG noted this response, but agreed that the current wording, “To opt out of NHS National data” was unclear and raised concerns that patients would not understand what they could opt-out of. Members agreed that the link to the National Data Opt-Out information could remain, but the text needed to be reworded to give a clearer explanation of the Opt-Out.

Members noted that “ecological validity” was given as a reason for not including information on the opt-out when the kit is sent out. The CAG asked that a definition for the term “ecological validity” was given to members.

The applicants advised that information about opt-out could not be sent with the kit as the national information is sent via a centralised process and could not be revised for

the specific regions involved in this study. The CAG noted this and raised no further queries.

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

The applicants explained that feedback had been sought. A training manual for patient navigators had been created, to ensure that the patient navigators appreciated and respected patient autonomy and their right to make an individual choice. A co-produced script was also created and included in the training manual.

Overall, patient and public members were positive about the approach taken, particularly the inclusion of a link to information and an animation, available in other languages.

The CAG noted the information provided and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. The text needs to be reworded to give a clearer explanation of the National Data Opt-Out.

2. Provide the CAG with the definition of “ecological validity”, as used in this application.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 20 February 2023.**

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

c. 23/CAG/0022 - Infant Feeding Survey 2023

Name	**Capacity**
Dr Sandra Duggan	CAG member
Dr Katie Harron	CAG member
Dr Murat Soncul	CAG alternate vice-chair
Mr Dayheem Sedighi	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application submitted by Ipsos UK on behalf of the Department for Health and Social Care (DHSC), sets out the purpose of conducting the 2023 Infant Feeding Survey, to understand how mothers in England feed their babies, where they get advice about feeding their babies, and about their pregnancy and lifestyle. ‘s251’ support is only requested for the purposes of contacting participants to seek implied consent to take part. Any process after the return of the questionnaire, is undertaken with implied consent as the legal basis under common law.

The Infant Feeding Survey is a well-established survey that has been running since 1975. This will be the 9th wave of the survey, the last survey being 2010. DHSC have commissioned Ipsos UK to run the survey process. The purpose of this application is to inform DHSC’s policy decision making processes, and will provide valuable information on infant feeding behaviours including breastfeeding, the use of foods and drinks other than breastmilk in infancy and other related matters. The survey is also a key commitment from government as part of the childhood obesity plan. It will provide vital information to monitor efficacy of current policies, and inform the development of new policies to ensure that all children are provided with the best start in life. The

anonymised dataset will be made available on the UK Data Archive for other organisations to access to support DHSC, and other organisations develop public policy and programmes to support mothers to breastfeed.

The 2023 survey will be based on a representative sample from NHS England (previously NHS Digital), of mothers who are selected from all births in England registered during a set period. Three phases of data collection with the same sample of mothers will be conducted. Mothers will be asked to complete one questionnaire when their baby is ten to thirteen weeks, one questionnaire when their baby is four to six months, and one questionnaire when their baby is eight to ten months old. The applicants have built in a sample boosting strategy that aims to boost the sample amongst those ethnic groups who are less likely to respond to questionnaires. A small incentive will also be offered to those from the most deprived quintile, measured using the indices of social deprivation at a lower-level super output area (LSOA).

The survey will follow a similar mixed method approach as the Maternity Survey 2021 and 2022, which is also carried out by Ipsos UK, with the same population. The contacts will be as follows;

Contact	**Type**	**Content of contact**	**Days from first mailing**
1	Postal	Invitation letter inviting the patient to take part online, Multi-language sheet	1
1.1	SMS	SMS reminder (if phone number available), 3 days after mailing 1	4
2	Postal	Reminder letter, Multilanguage sheet	7
2.1	SMS	SMS reminder (if phone number available), 3 days after mailing 2	10
3	Postal	Reminder letter, Paper questionnaire, Freepost return envelope, Multi-language sheet	17
4	Postal	Reminder letter, Multilanguage sheet	24

4.1	SMS	SMS reminder (if phone number available), 3 days after mailing 4	27

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

Confidential patient information requested

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

Cohort	Mothers aged 16 years or over at the time of delivery, who gave birth under the care of an NHS trust (including home births), in a given month (specific month contingent on the DARS processing times). Approximately 26,483 people will have invitations sent. Detailed inclusion criteria are in the CAG application form.
Data sources	1. NHS England (previously NHS Digital); a. Maternity Services Dataset b. Personal Demographics Service
Identifiers required for purposes of identifying the cohort and sending invitation to consent	1. Name 2. Address Fields including postcode 3. Mobile phone number 4. Patient unique survey identifier 5. Date of birth 6. Date of death 7. Ethnicity

Identifiers required for analysis purposes (disclosed to IPSOS UK prior to implied consent in place)	1. Patient unique survey identifier 2. NHS Site code (of birth) 3. Postcode – retained in full format for calculation of various variables (as per CQC surveys) 4. Mobile Phone indicator 5. Patient Date of Birth (Mother) 6. Patient Death Status (Mother) 7. Gender (Mother) 8. Ethnic group (Mother) 9. Actual delivery place 10. Delivery method 11. Maternal Critical Incident Indicator 12. Number of babies born at delivery 13. Patient date of birth (Baby / babies) 14. Baby phenotypic sex 15. Patient Death Status (Baby / babies) 16. Breast milk given for first feed (Baby / babies) 17. Baby admitted to neonatal critical care (Baby / babies) Analysis will be undertaken with implied consent

Confidentiality Advisory Group advice

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

1. **Please update the social media notification with details of how to opt out, and provide the updated notification to CAG for review.**

The applicant provided an updated notification, and the Sub-Committee were content with this response.

2. **Please submit the wording of the website notification to CAG for review.**

The applicant provided the wording of the website for review, and the Sub-Committee were content with this response.

3. **Please clarify the expected time period that confidential patient information will be retained by IPSOS UK before being destroyed, for mothers who do not return the questionnaire.**

The applicant explained that the length that 's251' support is required, as it will depend on when NHS England release the data. The applicant has therefore provided an estimated timescale of approximately 18 months, which will incorporate 12 months to conduct sampling and undertake the survey fieldwork, 3 months to publish the results of the survey, and then 3 final months after publication to ensure the project team is able to follow up on any queries or complaints. This is expected to be approximately 18 months from October 2023 to April 2025. The members were content with this response.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **NHS England, Ipsos UK, Formara Ltd and the Department of Health and Social Care (which covers GOV.UK Notify Service)** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (17 February 2023)

d. 23/CAG/0015 - Flatiron Health UK Oncology Real-World Database v2.0

Name	Capacity
Dr Tony Calland, MBE	CAG Chair

Dr Martin Andrew	CAG member
Mrs Diana Robbins	CAG member
Professor Sara Randall	CAG member
Dr Pauline Lyseight-Jones	CAG member
Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from Flatiron Health UK Ltd set out the purpose of creating a research database to collect real world data (RWD) for cancer patients aged 18 years and over.

Progress in cancer treatment is dependent upon high-quality evidence to demonstrate that specific interventions are safe and effective. Traditionally, evidence development has been through prospectively conducted clinical trials. However, “real world data” has the potential to contribute to understanding of what happens in routine clinical care.

The applicants, Flatiron Health UK Ltd, have partnered with Leeds Teaching Hospitals NHS Trust to create a representative, population-based cancer cohort. The database will be comprised of routinely collected retrospective data for patients aged 18 years and over who received treatment for cancer within Leeds Teaching Hospitals NHS Trust. Structured and unstructured data will be extracted from Trust clinical systems by members of the direct care team at Leeds Teaching Hospitals NHS Trust. The trust will transfer the confidential patient information to a “Landing Zone” within an NHS Trust Firewall. Flatiron Health UK Ltd will access the dataset to remove the identifiers from the data to create a pseudonymised dataset identified by a key and will be transferred to a “Joint Research Environment”, still within the trust firewall. There, Flatiron Health UK Ltd will undertake further processing to anonymise the data before transfer to the Flatiron Health UK Ltd Environment. All data processed by Flatiron Health UK Ltd after this point will be anonymised.

A recommendation for class 1, 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 treated within Leeds Teaching Hospitals NHS Trust, aged 18 years and over with a diagnosis of cancer, falling into one of four categories: newly diagnosed after pre-defined date (New patients), cancer patients diagnosed before pre-defined date and receiving ongoing care at NHS Trust (Active patients), cancer patients who were previously treated, but no longer actively receiving care at Leeds Teaching Hospitals NHS Trust (Inactive patients), and cancer patients who are deceased and were previously treated by the NHS Trust (Deceased patients). It is expected that the initial historical extract will ~32,000 cancer patients, with about 4,000-5000 new cancer patients will be added per year thereafter.
Data sources	1. Clinical information systems, including Electronic Health Records, chemotherapy ordering system, scheduling system, PACS and others
Identifiers required for linkage purposes	1. NHS Number
Identifiers required for analysis purposes	1. Gender 2. Ethnicity
Identifiers initially held in Landing Zone.	1. NHS Number 2. Hospital ID Number 3. Date of birth 4. Year of birth 5. Date of death 6. Postcode – unit level 7. Gender

	8. Ethnicity
Additional information	No identifiable information will exit Trust firewalls. Any information that does leave will be anonymised.

Confidentiality Advisory Group advice

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

1. **Detail the identifiable patient data items that Flatiron Health UK Ltd staff will be able to access remotely and provide further information on the safeguards that will be in place to maintain the confidentiality of this data.**

The applicants provided a List of Data Elements. Flatiron Health UK staff will have access to data whilst working from the Flatiron Health UK office and remotely. Flatiron Health UK staff will be given role-based access to the environments within the NHS Health and Social Care Network (HSCN) using VPN. This access is fully audited and restricted to serve the purposes of data access as underpinned by the data processing agreement between Leeds Teaching Hospitals NHS Trust and Flatiron Health UK. There will be strict technical and organisational safeguards in place for data the aforementioned data access as described in supporting document "Technical and Organisational controls".

The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. **Undertake further patient and patient involvement, specifically with the local community in Leeds on topics such as commercial relationship between Flatiron Health UK Ltd and Leeds Teaching Hospitals NHS Trust, the processing of confidential patient information without consent and the opt-out mechanism. This should include a minimum of 50 patients and progress reported six months from the date of the final outcome letter.**

The applicants agreed that Flatiron Health UK would conduct this activity, jointly with Leeds Teaching Hospitals NHS Trust, and report progress back to the CAG.

2. **A minimum of 2 lay members, with minimal experience in research and use of data, to be added to the Patient Voices Panel. Progress should be reported to CAG within 4 months from the date of the final outcome letter.**

The Patient Voices Panel (PVP) currently consists of 6 patients and carers. The group was created to reflect and respond to the voices and experiences of UK cancer patients and carers in Flatiron Health UK's work. The PVP contains individuals with lay knowledge, as it relates to research and data.

The applicants advised that they remain committed to continuing to grow the panel and include individuals with a mix of data experiences as well as other PPIE related experience to ensure it is a representative group.

The applicants queried whether the CAG was satisfied with the proposed recruitment strategy and that two further members with minimal experience and use of patient data did not need to be recruited. The applicants also noted that, based on their experience of recruiting members to the PVP, a 6-month time-frame may not allow enough time to identify a panel member, particularly with a specific background.

The CAG noted the response given and the details around the PVP and the justification for not seeking two additional members. The CAG agreed that further members needed to be recruited to the PVP. The two recruited should be articulate, confident in a mixed group, have no professional or senior position qualifications and no personal experience of any illness which may come into the scope of the application. They will represent the patients whose medical data is contributing to the Flatiron project without their consent and therefore need to be as impartial as possible

whilst able to make a meaningful and considered contribution to the work of Patients Voices. This requirement is obligatory and continued support under Regulation 5 is dependent on this condition being fulfilled.

The CAG has made these decisions to fulfil its role in ensuring that the use of confidential medical records from within the NHS are used transparently and ethically especially when large commercial organisations are involved.

An update on the recruitment process and progress in recruiting an additional two members needed to be provide within 4 months of the issuing of this Conditionally Supported outcome letter.

3. **A minimum of 1 lay member, with minimal experience in research and use of data, added to the Flatiron Research Oversight Committee. Progress should be reported to CAG in six months from the date of the final outcome letter.**

The applicants advised that Flatiron Health UK will conduct this activity and report progress back to the CAG.

4. **It is suggested that the patient notification materials are reworded to make it clear that opting out via the National Data Opt Out will opt out of their data being used for all secondary research and planning uses, not just this Flatiron application.**

The following sentence has been included “You can also opt out via the National Data Opt Out. However, this will result in opting your data out of being used for all NHS research and planning uses, not just from this Flatiron partnership.”.

This sentence has been added to the letter templates to active, inactive and new patients. This has also been added to the information leaflet. The CAG noted this and raised no further queries.

5. **Any future support issued will be for Leeds Teaching Hospitals NHS Foundation Trust only. Additional Trusts should be added by submission of an amendment.**

The applicants agreed with this condition. The CAG noted this and raised no further queries.

6. **Future amendments related to this application will be considered at a full meeting of the Confidentiality Advisory Group.**

The applicants agreed with this condition. The CAG noted this and raised no further queries.

7. **Future annual reviews related to this application will be considered at a full meeting of the Confidentiality Advisory Group.**

The applicants agreed with this condition. The CAG noted this and raised no further queries.

8. Favourable opinion from a Research Ethics Committee. **Confirmed: 16 February 2023**

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

   The NHS Digital **21/22** DSPT reviews **DSPT for Leeds Teaching Hospitals NHS Trust and Flatiron Health UK Ltd** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 23 January 2023)

e. 22/CAG/0158 - Investigation into sex-specific differences in mortality and complications following elective abdominal aortic aneurysm repair and association with pre-operative co-morbid status.

Name	Capacity
Dr Patrick Coyle	CAG vice-chair

Dr Rachel Knowles	CAG member
Ms Rose Payne	CAG member
Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from Imperial College London set out the purpose of medical research that seeks to examine the sex-specific different in co-morbid status and the standard of care prior to aortic surgery, and to explore association with long term post-operative outcomes.

An abdominal aortic aneurysm (AAA) is a swelling in part of the main vessel supplying blood to the lower body. AAA rupture can be fatal. To prevent this, AAA can be repaired by open abdominal surgery or by endovascular surgery. Women are more likely than men to die or suffer complications from elective AAA repair, and the reason for this is unknown. Current guidance for AAA treatment has been based on what works best in men, however women experience worse results. The applicants will use data collected in national datasets to compare the difference in health status and investigations pre-operatively, and outcomes following repair. The results will be used to identify whether there are key differences between outcomes of men and women, which require more detailed examination.

The National Vascular Registry (NVR) will extract a file containing items of confidential patient information for patients who have undergone an aortic repair. This will be disclosed to NHS Digital for linkage to the Civil Registration Deaths, HES admitted patient care, Medicines dispenses in primary care datasets. The NVR and NHS Digital will each disclose a pseudonymised dataset to the Big Data and Analysis Unit (BDAU) at Imperial College London. Both datasets will have a unique patient identifier applied to allow linkage of the two datasets.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over who have undergone an aortic aneurysm repair. Approximately 31,500 patients will be included.
Data sources	2. The National Vascular Registry, held by the Royal College of Surgeons of England 3. Civil Registration Deaths, HES admitted patient care, Medicines dispenses in primary care, datasets held by NHS Digital
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode – unit level 4. Sex
Identifiers required for analysis purposes	1. Gender

Confidentiality Advisory Group advice

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

1. **The following revisions need to be made to the Privacy Notice:**

    a. **The section "Your Rights" needs to be rewritten to make it clear that patients can opt-out. Members suggested that patients are advised to opt-out via the NVR.**

b. **Any limits on removal, such as the inability to remove data from ongoing or completed analyses, need to be explained.**

The applicant provided a revised Privacy Notice. This had been rewritten to make the opt-out information clear and explain any limits on removal. The CAG noted this and raised no further queries.

2. **A patient and public involvement group needs to review the patient notification strategy and materials.**

The patient and public involvement group had reviewed the patient information sheet. The CAG noted a possible error in the document. The applicants provided an amended patient information sheet, which was accepted by the CAG.

3. **The specific issue of use of confidential patient information without consent needs to be discussed during patient and public involvement and feedback from the discussion provided to CAG.**

The applicants provided a PPIE involvement tracker, which detailed the discussion of the project during the NIHR DF at multiple time points and PPIE feedback on the patient information sheet. The CAG requested further clarification on the discussions that had taken place, which the applicant provided. The CAG noted this and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 16 January 2023.**

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

   The NHS Digital **2021/22** DSPT reviews for **NHS Digital and National Vascular Registry (Royal College of Surgeons of England)** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 November 2022).

f. 23/CAG/0002 - Haematological inflammatory markers and survival in mesothelioma

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

Context

Purpose of application

This application from University Hospitals of Leicester NHS Trust set out the purpose of medical research that seeks to contribute to the body of evidence on the role on inflammation in MPM prognosis, specifically within a UK population, where very few studies have been conducted in this regard.

Malignant pleural mesothelioma (MPM) is an uncommon cancer which is related to previous asbestos exposure. The disease has a poor survival, with studies quoting a median overall survival (OS) time of 9–17 months regardless of the tumour stage at diagnosis. The British Thoracic Society mesothelioma guideline quotes a high neutrophil-lymphocyte ratio (NLR) as an independent predictor of poor survival in MPM.

However, there is limited evidence on other prognostic inflammatory markers such as the platelet-lymphocyte ratio (PLR), lymphocyte-monocyte ratio (LMR) and systemic immune inflammation index (SII) in the literature. These markers have been well-studied in other cancer sites, such as lung cancer, and have been associated with similar poor survival.

Confidential patient information from the mesothelioma MDT database at the University Hospitals of Leicester NHS Trust will be disclosed to the Chief Investigator, who is not considered direct care team, and therefore requires 's251' support. The Chief Investigator will use the hospital number to obtain data from medical records of all patients with a pleural mesothelioma diagnosis from 2014-2021 (expected to number 250 to 300 patients). Date of death will be used to calculate overall survival time from diagnosis in days. It will be deleted from the database once this has been calculated, and analysis will be undertaken on an effectively anonymous dataset.

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

Confidential patient information requested

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

Cohort	All University Hospitals of Leicester NHS Trust patients aged 18 years and above, with a pleural mesothelioma diagnosis from 2014-2021 (expected to number around 250-300 patients)
Data sources	University Hospitals of Leicester NHS Trust 1. Mesothelioma MDT database (local cancer register) 2. Patient medical records
Identifiers required for linkage purposes	1. Hospital number

Identifiers required for analysis purposes	1. Date of death will be used to calculate overall survival time from diagnosis in days. It will be deleted from the database once this has been calculated.

Confidentiality Advisory Group advice

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

1. **Please undertake further patient and public involvement with 5 or more cancer survivors and/or members of cancer support groups. This can be by video conference or email, and should focus specifically around the use of confidential patient information without consent and feedback from this provided to the CAG.**

The applicant provided an overview of the patient and public involvement carried out and a lay summary of the information provided to attendees at a Meso UK PPI group. The CAG reviewed this and noted it was unclear whether the specific question about use of confidential patient information without consent had been put to the PPI group. Members asked that this specific question was put to the CEO of Mesothelioma UK and their response provided back to the CAG within 3 months of the issuing of this letter.

2. **Please provide a poster to display in relevant areas in the clinic so information about the study would be displayed, and that patients can choose to opt out if they wish to.**

The CAG reviewed the poster and noted that the opt-out was mentioned towards the bottom of the leaflet and agreed it would be better if there was also a proper paragraph in the text about opting out of the use of eligible patient data.

A further revised poster was provided. The CAG was largely satisfied with the poster, however a potential typographical error in paragraph 5 was noted. The CAG also asked that telephone and postal contacts were provided, for patients to register dissent to use of their information, in addition to the email address.

3. **Please confirm whether the Chief Investigator actually receives the Date of Death and deletes it once the survival time is calculated, or whether survival time is calculated by the cancer centre data manager.**

The applicant advised that patients date of death will be obtained from patient records and used to calculate survival time. The date of death will not be included in the data collection sheet. The CAG noted this response and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. The poster needs to be revised, as below:

    a. The typographical error in paragraph 5, “No identifying data will be retained or presenting” needs to be corrected.

    b. A telephone and postal address needs to be provided, for patients to make contact and register dissent to use of their information.

2. The specific question about the acceptability of use of confidential patient information needs to be put to the CEO of Mesothelioma UK and their response provided back to the CAG within 3 months of the issuing of this letter.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 10 January 2023**

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 **21/22** DSPT review for **University Hospitals of Leicester NHS Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (24 January 2023)

g. 23/CAG/0017 - Application of the Clinithink Natural Language Processing tool and Machine Learning methods to Clinical Notes for the Screening of Lung Cancer.

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Dr Sandra Duggan	CAG member
Professor Lorna Fraser	CAG member
Dr Katie Harron	CAG member
Mr Tony Kane	CAG member
Professor Sara Randall	CAG member
Ms Diana Robbins	CAG member
Mr Umar Sabat	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Barts Health NHS Trust set out the purpose of medical research which aims to examine the feasibility of Clinithink, a clinical Natural Language Processing (NLP) tool, to extract SNOMED codes from GP and hospital notes of patients referred for chest x-rays, and to use the extracted data to identify risk factors for lung cancer and to develop diagnostic models for GPs for early-stage lung cancer, and prognostic models for lung cancer outcomes. The study is a retrospective observational cohort study, and uses an NLP tool to anonymise free-text notes and extract relevant clinical information. 's251' support is requested because the

identification of eligible patients and the running of free-text notes through the NLP software is undertaken by 2 researchers who are not considered direct care team, and in undertaking these activities these individuals will be viewing confidential patient information.

Around 48,500 new cases of lung cancer are diagnosed each year in the UK. Death from lung cancer is the most common of all cancers, with only 10% of patients surviving for ten or more years. Most lung cancer is diagnosed in the later stages of the disease, making treatment more difficult and putting strain on the NHS. However, when diagnosed sooner, treatment is much more effective, with survival rates increasing to 30-80% from 2-15%. Therefore, this research aims to develop tools to identify patients at high risk of lung cancer before they otherwise would be in the clinical pathway. At present, the process for referral is heavily reliant on the referrer's personal judgment and ability to recognise symptoms, potentially delaying a diagnosis or misdiagnosing the cancer as a less serious ailment. Medical notes are rich sources of information, however, due to their unstructured nature, extraction of relevant information from free-text notes is a time and labour intensive process. For this reason, the use of unstructured data for the screening of many diseases is largely unexplored. Clinithink is an NLP tool that extracts requested information from medical notes, formatting the output into a structured dataset (SNOMED-codes) which can be more easily analysed. In implementing a tool such as Clinithink, the limitations associated with unstructured data could be mitigated. The intention of this study is to investigate the viability of using the Clinithink NLP tool to extract information from the medical notes of a targeted demographic of patients and test the viability of then applying newly developed predictive models to the extracted information to identify which patients are risk of lung cancer, so that lung cancer can be detected, and patients can be treated earlier and more effectively, and lives are saved.

Two researchers employed by Barts Health NHS Trust, who are not considered direct care team, will identify eligible patients by searching the Trust records via the inclusion criteria, recording the relevant NHS numbers. The National Data Opt Out will then be applied. Following identification of participants, a 'third party' who is a member of the direct care team within Barts Health NHS Trust, who is not a member of the study team, will link the NHS numbers to secondary care data, and send a request to the Data Discovery Service (held at North East London ICB), in order to gain access to primary care free-text notes. The third party will then remove the NHS number and replace it with a pseudonymous 'PERSON_ID', and disclose the free text data back to the applicants, alongside pseudonymous structured data extracted from medical records. Barts Health NHS Trust data warehouse team will hold the pseudonymisation key. 's251' support is still required at this stage, as although the structured data is

pseudonymised, the researchers still have access to the free text documents provided, and it is expected that these may contain confidential patient information.

Free-text information will then be fed into Clinithink's NLP tool, Clix, by the researchers. The tool will extract an anonymised dataset including biopsychosocial variables from the text, and will not extract sensitive and personal information which could be used to identify a patient. In order to verify that Clinithink has performed this task correctly, the direct care team will audit the data extracted from the free-text to ensure it is free from confidential patient information. This will involve cross-referencing a random sample of patient notes against the information extracted by Clinithink. Should identifiable information be extracted, the NLP queries will be amended and the extraction process re-run. Following a satisfactory audit, the free-text information will be deleted. The retained data will then be analysed and used to develop a series of diagnostic and prognostic models for lung cancer. Upon conclusion of the study, the generated research datasets will be stored in the Trust Corporate Records Centre for 5 years, in accordance with the sponsors archiving SOP and the UK Policy Framework for Health and Social Care Research.

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

Confidential patient information requested

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

Cohort	all patients aged ≥ 40 years old, who have received a chest x-ray at any of the hospitals within Barts Health NHS Trust between 01 Jan 2016 – 31 Dec 2019 AND 01 Jan 2022 – 31 Dec 2022, with at least one primary or secondary care data entry after the initial chest x-ray

	Approximately 250000 individuals (5000 patients with a positive diagnosis for lung cancer and 245000 with no diagnosis of lung cancer)
Data sources	1. Barts Health NHS Trust; a. Secondary care data; i. Electronic medical records ii. The referral letter for the chest x-ray iii. Report from the chest x-ray iv. Free-text medical records 1-year prior to the chest x-ray v. Free-text pathology records for the subsequent 3 years and 364 days after the chest x-ray 2. North East London ICB (data processor Voror Health Technologies Ltd); a. Discovery Data service - Primary care data; (primary care facilities across Northeast London) i. Free-text medical records 1-year prior to the chest x-ray ii. The subsequent free-text GP record following the scan
Identifiers required for identification of eligibility purposes, and running through NLP	5. NHS Number 6. Full Health Record (free text notes) 7. Date of death
Identifiers required for analysis purposes	Analysis will be on an effectively anonymised dataset – 1. sex 2. ethnicity 3. occupation 4. post code will be modified to Indices of social deprivation

	5. Date of death will be modified to time from diagnosis to death

Confidentiality Advisory Group advice

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

1. **The patient information materials need to be revised as follows;**

    a) **Please add telephone contacts for local data opt-out.**

    b) **Please make the study specific opt out option more prominent, and alter the paragraph on the National Data Opt Out to merely state that the study will respect any registered National Data Opt Outs.**

    c) **Please amend the typographical error in the Participant Information Sheet 'no aspect of <u>you</u> care'.**

    d) **Further methods of patient notification also need to be developed, adopting a layered approach, making information available in brief accessible leaflets as well as online. Please provide posters in clinical areas including QR codes or links leading to further information on the website.**

    e) **Please change the wording where mentioned 'CAG Approval' as CAG is not the decision maker, it is more accurate to state that the application has been supported by the Health Research Authority (HRA) on advice from the Confidentiality Advisory Group (CAG).**

The applicant provided an updated set of patient notification documents for review. A summary leaflet will be made available to the oncology and respiratory teams within the Trust and handed out at future PPIE events. Additionally, a poster has been created. The CAG were content with these documents and changes made as per CAG advice.

2. **The CAG noted that they were unclear whether Barts Health NHS Trust data warehouse team was considered to be direct clinical team. Please confirm**

whether CAG support is required for the retention of the key by Barts Health NHS Trust data warehouse team.

The applicant confirmed that the data warehouse team are considered to be a direct are team given the nature of their job roles. Therefore, Regulation 5 support would not be required for the retention of the key. The CAG were content with this response.

3. **Please provide the Favourable Opinion from the REC when available**

The applicant provided this as per standard condition of support.

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 23 March 2023**

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

   The NHS England **21/22** DSPT review for **Barts Health NHS Trust, Voror Health Technologies Ltd** and **North East London ICB** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (03 February 2023)

2. New Amendments

21/CAG/0089 – ReSPECT in primary care

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

Context

Amendment request

This application aims to evaluate the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) process for adults in primary care, to determine how, when and why it is used, and what effect it has on patient treatment and care. The application has 's251' support to allow (as part of Work packages 1 & 3) the research team, who are not considered members of the direct care team, to view confidential patient information while extracting a pseudonymised set of demographic data from GP records. The applicants anticipated that this will often be done by members of the direct care team, however support is in place should this not be possible.

No 's251' support is currently in place for data extraction from care homes as this was planned to be undertaken by care home staff.

The purpose of collecting these data from GP practices was to assess congruence between clinical recommendations on the patient ReSPECT form with decisions made during any acute clinical episode in the following six months. Initial data collection has found that much lower numbers of ReSPECT forms and associated acute clinical episodes were identified than expected, using GP practice records.

This amendment sought support to extend the 's251' support from GP practices to 3 care homes as a feasibility exercise. Applicants will explore whether accessing residents' ReSPECT forms and their care home record to identify acute medical events, would enable them to answer the research question on congruence. Access would be

required to care home residents' ReSPECT forms and care records. Care homes are involved in the main project but were not included within the scope of the original CAG application, as the expectation was that all research activities undertaken within care homes would be conducted by the direct care team. However, the study teams' recent experience of recruiting care homes to the main project is that these organisations are unlikely to have the capacity and capability to complete the necessary work, so the investigators propose for a member of the study team (who is not part of the direct care team) to undertake these tasks.

Applicants have provided patient notification designed for care homes, which are based on their originally supported documents.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair was content to support this amendment request, noting it appeared reasonable to extend the 's251' support to care homes.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   Due to the number of participating care providers involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 16 February 2023**

19/CAG/0136 – Acute Leukemia in Pregnancy Registry Study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the Hull and East Yorkshire Hospitals NHS Trust aims to establish a research database focused on women who were diagnosed with acute leukaemia or high-risk myelodysplasia in pregnancy or who have later conceived after receiving previous treatment for either condition.

This amendment sought support to extend the duration of support required until end of August 2023 to ensure that all the data can be cleaned and analysed prior to anonymising, as per the application.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

Confirmed: The CAT team has not undertaken a check of the security assurances at each site, as the study has support for over 5 participating organisations. This is the responsibility of the applicant to ensure that these are in place.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 19 October 2022 that Favourable ethical opinion for the research database continues to apply until 02 August 2024

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application is investigating the feasibility, effectiveness and cost-effectiveness of regularly testing care home staff for COVID-19 to protect residents from severe infection and prevent outbreaks. 's251' support is currently in place for the disclosure of confidential patient information (regarding residents admitted to hospital) from care homes to NHS England, for the purposes of linkage to the NHSE Foundry (COVID-19 datastore) (which will then be pseudonymised and disclosed to UCL). The CAG outcome letter provides 's251' support for the following care home sites; 280 participating care homes records (from the following providers):

- Four Seasons Healthcare(FSHC)
- HC-One
- Orders of St John Care Trust (OSJCT)

This amendment sought support to include four more care home providers as additional data processors for the application;

• Risedale Estates Limited

• Greensleeves Care

• Black Swan Care Group

• Bupa

The justification for this amendment is to ensure that the research question is able to be answered, as more sites are required in order to do so.

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

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

Specific conditions of support

The following sets out the specific conditions of support.

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

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

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

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 30 January 2023

22/CAG/0019 – CUREd+: Centre for Urgent and Emergency Care Research Database – refresh

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application updates and extends the CUREd Research Database (18/CAG/0126), to include more recent data and to extend the geographical area covered by the dataset. The CUREd Research Database refresh expanded the hospital data to cover all of England, updated the linked ambulance service data, added death registration data, reduced variation within the hospital data, reduced the amount of confidential patient information processed and retained by University of Sheffield, and will enable further research on a number of Urgent and Emergency Care (UEC) related topics.

's251' support is in place for the disclosure of confidential patient information (from patients in CUREd research database 2011 – 2017) from University of Sheffield, and confidential patient information (from patients treated 2017-2023) from Yorkshire Ambulance Service (YAS) to NHS England (previously NHS Digital) in order to link to clinical datasets and disclose confidential patient information back to the applicant at University of Sheffield. There are also other elements to the support that are not relevant to this amendment.

The cohort and specified linkage was proposed to be as follows;

Cohort	Patient episodes of care between 1st April 2011 and 31st March 2023

	Cohort A: Patients who 1) contacted or received care from the emergency ambulance service provided by Yorkshire Ambulance Service (YAS) NHS Trust, or 2) contacted the NHS 111 telephone triage service provided by YAS Cohort B: Patients who 1) received unscheduled care at a Walk-in Centre, Minor Injuries Unit, Urgent Care Centre or Emergency Department in England, or, 2) received inpatient or outpatient NHS hospital care in England, or 3) received care from Mental Health Services in England Cohort C: Patients who 1) are in cohort A, or 2) are in cohort B, and whose care was provided by a Trust in the Yorkshire and Humber region Approximate number of patients estimated as 80 million in Cohort B, plus additional minimal numbers in cohort A and C.

	(however the 80 million figure is based on number of unique NHS England (previously Digital) identifiers, and this may represent a lower number of individual patients)
Data sources	1. University of Sheffield - School of Health and Related Research (ScHARR) a. the YAS clinical data (999 and NHS111) extracted from CUREd Research Database", between 2011 and 2017 b. patient identifiers for the existing YAS cohort of patients from the CUREd database 2. NHS England (previously Digital) a. For cohort B: i. Hospital Episode Statistics (HES); 1. Emergency Care Data Set (ECDS) 2. Accident & Emergency (A&E) 3. Outpatient (OP) 4. Admitted Patient Care (APC) ii. Mental Health Services Data Set (MHSDS) iii. Demographic, and iv. Civil Registration – death data (ONS Mortality) b. For cohort C: i. Medicines Dispensed in Primary Care data, ii. and address information iii. Demographic, and iv. Civil Registration – death data (ONS Mortality) 3. Yorkshire Ambulance Service – (2017-2023) (cohort A) a. electronic Patient Records (ePR), b. Computer Aided Dispatch (CAD) and c. NHS111

This amendment sought support to remove cohort C entirely. This is due to time constraints experienced by NHS England (previously NHS Digital). This amendment also sought support for NHS England (previously NHS Digital) to link cohort A (instead

of cohort C) to Medicines Dispensed in Primary Care data, address information, demographics, and civil registration – deaths data. Cohort A are a subset of the original cohort C, which is no longer required and therefore this amendment proposes a less disclosive method than the original support.

The applicants have provided an updated data flow diagram which reflects these changes, and the patient notification documents have also been updated.

The updated cohort and data sources are as follows;

Cohort	Patient episodes of care between 1st April 2011 and 31st March 2023 Cohort A: Patients who 1) contacted or received care from the emergency ambulance service provided by Yorkshire Ambulance Service (YAS) NHS Trust, or 2) contacted the NHS 111 telephone triage service provided by YAS Cohort B: Patients who 1) received unscheduled care at a Walk-in Centre, Minor Injuries Unit, Urgent Care Centre or Emergency Department in England, or, 2) received inpatient or outpatient NHS hospital care in England, or 3) received care from Mental Health Services in England

	Approximate number of patients estimated as 80 million in Cohort B, plus additional minimal numbers in cohort A. (however the 80 million figure is based on number of unique NHS England (previously Digital) identifiers, and this may represent a lower number of individual patients)
Data sources	1. University of Sheffield - School of Health and Related Research (ScHARR) a. the YAS clinical data (999 and NHS111) extracted from CUREd Research Database", between 2011 and 2017 b. patient identifiers for the existing YAS cohort of patients from the CUREd database 2. NHS England (previously Digital) a. For cohort A: i. Medicines Dispensed in Primary Care data, ii. and address information iii. Demographic, and iv. Civil Registration – death data (ONS Mortality) b. For cohort B: i. Hospital Episode Statistics (HES); 1. Emergency Care Data Set (ECDS) 2. Accident & Emergency (A&E) 3. Outpatient (OP) 4. Admitted Patient Care (APC) ii. Mental Health Services Data Set (MHSDS) iii. Demographic, and iv. Civil Registration – death data (ONS Mortality) 3. Yorkshire Ambulance Service – (2017-2023) (cohort A) a. electronic Patient Records (ePR), b. Computer Aided Dispatch (CAD) and c. NHS111

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding the amendment, noting it was less disclosive than the original design.

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **University of Sheffield - School of Health and Related Research (8D715 – SHRR), Yorkshire Ambulance Service (RX8) and NHS Digital** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 10 March 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed no review required 14 February 2023**

19/CAG/0196 – Evaluating prescribing safety indicators embedded in computerised clinical decision support software OptimiseRx

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow ResearchOne and NHS England (previously NHS Digital) to generate a SALT link key to facilitate linkage between primary care data from GP practices and HES, ONS and IMD datasets at NHS England (previously NHS Digital). The aim of the application is to evaluate the effectiveness of the computerised clinical decision support system OptimiseRx on improving prescribing safety in general practices and the associated costs to the NHS.

This amendment sought support to extend the duration of the study to 31 December 2023, as NIHR have approved an extension to the Programme Grant, in order to complete the analyses.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. No queries were raised regarding this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed non substantial 24 February 2023.**

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

The NHS England **21/22** DSPT reviews for **NHS Digital & The Phoenix Partnership (TPP)** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 09 March 2023)

22/CAG/0088 – Evaluating ICON: A mixed methods study to assess the impact of the ICON programme on coping strategies for carers of crying babies, and rates of abusive head trauma in infants aged under one year.

Name	Capacity
Professor William Bernal	CAG alternate Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to evaluate the effectiveness of the ICON programme in reducing incidence of abusive head trauma (AHT) in young infants. 's251' support is currently in place to allow Trauma and Audit Research Network (TARN) dataset, the National Child Mortality Database (NCMD), and the Paediatric Intensive Care Audit Network (PICANet) to disclose confidential patient information for patients meeting the inclusion criteria to NHS England (previously NHS Digital) for data linkage with the Hospital Episode Statistics (HES), Admitted Patient Care (APC), Emergency Care (ECDS) and Diagnostic Imaging Datasets (DID).

This amendment sought support to include ONS mortality data as an additional data source from NHS England (previously NHS Digital), instead of National Child Mortality Database (NCMD), as the applicants have been unable to use this data source. This therefore is a less disclosive design than originally supported.

Relevant updates have been made to patient notification documentation.

Confidentiality Advisory Group advice
The amendment requested was considered by Chair's Action. The Alternate Vice Chair was content to support this amendment, noting it will reduce rather than increase any risk of inadvertent disclosure.

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   Due to the number of organisations involved it is the responsibility of University Hospitals Bristol and Weston NHS Foundation Trust, as controller, to ensure that organisations processing confidential patient information for the purposes of this CAG application meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial by email 07 February 2023**

22/CAG/0103 – Supporting the NHS Long Term Plan: An evaluation of the implementation and impact of NHS-funded tobacco dependence services

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow research staff at participating trusts to access confidential patient information in order to identify eligible patients and extract a pseudonymised dataset. Hospital records will be accessed to determine the number of smokers who have been offered and used tobacco dependence services and to calculate the cost of providing the service.

In this amendment, the applicants are seeking to make multiple changes to the protocol. The majority of these are not relevant for CAG as they do not affect the scope of 's251' support, for example, changes regarding consented patient and staff interviews. The REC have already confirmed a Favourable Opinion for these changes, and these are accepted by CAG as notifications only.

The only change relevant to the 's251' support is to amend the length of time that confidential patient information will be accessed without consent. The applicants have made a change to the protocol to clarify that data is being collected for 'up to 10-months' instead of 'for 10-months'. Applicants had originally proposed receiving 10-months (consecutively) of pseudonymised patient level data from the each of the participating NHS Trusts, however this is now revised to indicate that up-to 10-months of data will be collected, as applicants recognise that they are most likely to receive 7-months of patient level data from participating NHS Trusts given the time gap between data collection and reporting (an up to 8-week gap).

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the amendment was in the public interest, noting that this is less disclosive than the original design.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

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

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 23 February 2023**

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This amendment sought support for an end of study extension from 30 June 2023 to 30 June 2028, following an extension approval to programme grant funding the study by funder, Cancer Research UK, to allow continued analyses.

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

support to extend the end of the study until 30 June 2028 to allow further analyses, however ‘s251’ support is required until 30 June 2038.

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

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT review for **Imperial College London, Faculty of Medicine, Cancer Screening and Prevention Research Group** was confirmed as ‘Standards Met’ on the NHS England DSPT Tracker (checked 10 March 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 02 March 2023

18/CAG/0184 – Using National Congenital Heart Diseases Audit data to explore the impact of non-medical risk factors on late post-operative outcomes for children with complex congenital heart defects.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to undertake follow-up of children who underwent surgery for complex heart defect since 2000 to assess longer term health outcomes in this patient group. ‘s251’ support is in place to allow the disclosure of specified confidential patient information from the National Congenital Heart Diseases Audit to NHS England (previously NHS Digital) to facilitate linkage with ONS mortality information, and the return of this data for linkage with wider clinical information.

This amendment sought support to extend the duration of ‘s251’ support from 27 May 2023 to 30 September 2024, in order to complete analyses.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 21/22 DSPT reviews for **UCL School of Life and Medical Sciences Data Safe Haven, NHS Arden and Greater East Midland Commissioning Support Unit (Arden & GEM), Redcentric (Harrogate)**, & **NHS Digital** were confirmed as ‘**Standards Met’** on the NHS England DSPT Tracker (checked 10 March 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 22 February 2023

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

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

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

This amendment is to include a further purpose to the LeDeR application, to allow a pseudonymous data set to be disclosed to University of Exeter. This data will be effectively anonymous as the University of Exeter does not have the ability to re-identify, and therefore University of Exeter is not a data processor for the purposes of the CAG application. The purpose of this disclosure is for University of Exeter to undertake analysis, to identify contributory factors relating to deaths of people with learning disability from epilepsy and to indicate some of the service improvements that are required. This relates to only those people with learning disabilities (all ages) who died in 2018-2020 and who had epilepsy recorded as a long-term condition (n= 3,358), and people with learning disabilities (all ages) who died in 2018-2020 and who had epilepsy recorded as a cause of death anywhere on Part I of their MCCD (n=471). The data items disclosed are listed in the amendment documents, and no items of confidential patient information is included in this disclosure. An amendment is required in order for LeDeR to disclose this data, as confidential patient information was collected under ‘s251’ support, and this is required to be processed in order to provide University of Exeter an effectively anonymous dataset for analysis.

Justification for the amendment has been provided. The applicant reasons that it is essential that the NHS does all it can to reduce health inequalities in the population. The NHS Long term Plan states its intention to take action on prevention and health inequalities, and to help people with a learning disability and autistic people live longer healthier lives. This amendment will aid that aim.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT), as this amendment was no more disclosive than the main LeDeR application. No queries were raised regarding this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **University of Central Lancashire (EE133869-CBMS), NHS England (X24), North of England CSU (0AR), Kings College London (EE133874-ROSALIND) and South Central and West Commissioning Support Unit (0DF)** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 10 March 2023)

CAG 8-03(PR2)/2013 - UK Register of Fatal anaphylactic reactions

Name	Capacity

Dr Patrick Coyle	CAG Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This service evaluation application from Manchester University NHS Foundation Trust aims to review deaths from anaphylactic reactions, evaluating whether treatment was given, if so what treatment and why it was ineffective. A recommendation for class 2, 4 and 6 support was requested to cover linking data on an existing locally held database of deceased patients with data held by coroners. 's251' support was provided broadly, and it was assumed that 's251' support was in place for certain data sources and processors, however, the applicant is now required to clarify some aspects of the activities to ensure 's251' support is in place for the data flows.

This amendment sought support to include GPs and NHS Trusts as data processors alongside coroners. This is because there have been difficulties in receiving all the necessary information from Coroners, as during the pandemic, many cases were not taken for inquest.

The amendment also sought support to clarify that 's251' support is in place for the applicant to receive data of deceased individuals from anaphylactic reactions, in the form of a copy of the medical record, to ensure all the relevant information is able to be gleaned by the applicant. This is because the applicant has found they are not receiving the necessary information, due to a shortage of staff who can reliably identify the relevant information. This then leads to multiple communications with often well-meaning, but futile responses received. This amendment therefore will reduce the burden on the NHS and improve the quality of the data in this audit. The medical notes are destroyed once the relevant information is extracted.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair was content to recommend support for the amendment, noting that the amendments are justified in order to improve ascertainment and data quality and completion.

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 21/22 DSPT review for **Manchester University NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 08 March 2023)

22/CAG/0007 – Prison healthcare, focusing on natural and other non-natural deaths

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from NCEPOD set out the purpose of a confidential enquiry to review the clinical healthcare provided to prisoners. The application currently has 's251' support to allow the disclosure of confidential patient information from hospital records and SystmOne via Primary Care Support England/The Phoenix Partnership to NCEPOD and onward sending to the clinicians to undertake the peer review, and to allow the NCEPOD team to send questionnaires to the clinicians who cared for the patient.

This amendment sought support to clarify that The Health Foundation is not a data processor for this study, as they have provided the funding only. They are listed as requiring a DSPT in the original outcome letter and this is not required.

This amendment also sought support to amend the data flows, to clarify that NHS England and Improvement is now a data processor, as they are now providing the clinical reviews and case notes from SystmOne instead of Primary Care Support England/The Phoenix Partnership. This is via direct contact between NHSE/I and the healthcare providers, and individual DSPTs will not be checked for these, as there are more than 5 organisations. Initially it was hoped that applicants could obtain the notes from Primary Care Support England, however this proved not as easy as expected. Therefore Primary Care Support England/The Phoenix Partnership are now removed from the application as data processors.

The applicant has provided an updated data flow diagram to describe the new flows.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair was content to support this amendment, noting there are good organisational reasons for the change in data flows.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England **21/22** DSPT reviews for **NCEPOD** & **NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 09 March 2023)

22/CAG/0103 – Supporting the NHS Long Term Plan: An evaluation of the implementation and impact of NHS-funded tobacco dependence services

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow research staff at participating trusts to access confidential patient information in order to identify eligible patients and extract a pseudonymised dataset. Hospital records will be accessed to determine the number of smokers who have been offered and used tobacco dependence services and to calculate the cost of providing the service.

This amendment sought to include University Hospital Coventry and Warwickshire NHS Trust (UHCW) and Bradford Teaching Hospitals NHS Foundation Trust (BTHFT) as participating sites and data processors for the application.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

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

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 10 March 2023**

22/CAG/0095 – UK Early Life Cohort Feasibility Study

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have support to allow the disclosure of confidential patient information from NHS Digital to Ipsos Mori, who will send information about the study to selected patients, in order for them to consent. The applicants have 's251' support for a one-stage recruitment approach, of Ipsos Mori sending one advance letter and booklet to the selected sample, with the option to opt out at that stage.

This amendment sought support to add an additional prior opt out letter, which would also be sent by Ipsos Mori, and which applicants refer to as a modified two-stage approach. This gives families the opportunity to opt-out well in advance of interviewer home visits, reflecting public dialogue research results.

Applicants have provided a revised data flow diagram which includes this additional step, and the data flows otherwise remain the same. The new initial opt out letter has been provided, and amended further communications.

The amendment to the REC also covered multiple other changes which do not appear to change the 's251' support provided, and therefore all other changes listed in the amendment are accepted as notifications to CAG.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chairs' Action. The Vice-Chair was content to support the amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 27 February 2023.**

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

   The NHS England **21/22** DSPT reviews for **University College London (EE133902-SLMS), Ipsos Mori and NHS Digital** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 20 March 2023)

22/CAG/0051 – Our Future Health

Name	Capacity
Dr Tony Calland, MBE	CAG Chair

Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from Our Future Health Ltd aims to create a research tissue bank for use in research into early detection of disease. The aim is to speed up the discovery of new methods of early disease detection, and the evaluation of new diagnostic tools, to help identify and treat diseases early, with the hope that this will lead to better patient outcomes. The applicants have 's251' support to allow the disclosure of confidential patient information from NHS England (previously NHS Digital) to APS Group, the contracted mailing supplier, to facilitate the sending of invitation letters to selected patients. The initial CAG support provided support for approximately 3 million patients to be contacted. A recently supported amendment allowed for approximately 12 million patients to be contacted.

This amendment sought support for an additional 4 million patients to be contacted, to make a total of approximately 16 million people. This amendment is sought due to the increased capacity of both clinic availability, and invitation mailouts. This means applicants can invite individuals at a higher rate, and greater scale to support achieving recruitment targets.

Our Future Health aim to recruit up to 5 million adults from across the UK to create a cohort of people who have consented to participate in the research. The applicant has confirmed that this is not changing.

Potential participants will be identified and contacted in various ways, including: identification by staff in primary and secondary care, by NHS blood donation, direct recruitment and survey based sampling. Participants in existing research studies will also be contacted about this study. These methods of recruitment are outside the scope of the support sought, as confidential patient information will be processed only by those with an existing legal basis.

The applicants will also identify and contact patients in England via DigiTrials as described above. The assumed response rate was 5% and the applicants originally expected around 150,000 patients will be recruited via this method. This was the estimated when 3 million patients were to receive invites. The total number of 5 million people consented is not changing, however the proportion that the applicants expect to be included via the 's251' supported method is increasing to more than 150,000.

This amendment is submitted as an interim increase, as suggested by CAG as a result of a deferred amendment for a larger increase, and therefore should be read in conjunction with the deferred amendment outcome, issued 21 March 2023.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs Action. The Chair was content to support this amendment, as per advice in the deferred amendment outcome letter, issued 21 March 2023.

The Chair noted for the minutes that an amendment request for 45 million patients to be contacted had been deferred, and therefore this additional extension of 4 million was suggested to avoid a significant wastage of money which had already been committed to set up all the clinic visits for consented patient. The CAG required more evidence of the public benefit to balance against a very substantial breach in terms of numbers, and further information regarding the other methods of recruitment which were being used. These practical alternatives needed to be taken into the consideration as the numbers in the breach rose, and CAG are therefore expecting further amendments with additional information regarding these points.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS England **2021/22** DSPT review for **APS Group Ltd** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 17 February 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed on 22 February 2023 that this is covered as part of REC Favourable Opinion provided on 23 May 2022 (AM03 – protocol update)**

18/CAG/0159 – Housing, family and environmental risk factors for hospital admissions in children

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants are seeking support to extend the duration of 's251' support until 31 December 2025. This is due to delays caused by the Covid-19 pandemic.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. No queries were raised regarding this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

The NHS England 21/22 DSPT reviews for **the Office for National Statistics, University College London – School of Life and Medical Sciences & NHS Digital** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 28 February 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 28 March 2023

18/CAG/0159 – Housing, family and environmental risk factors for hospital admissions in children

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants are seeking support to clarify that injury admissions are an outcome with regards to this study. The applicant already has 's251' support in place regarding emergency hospital admissions in children. These admissions include admissions for acute infections and injuries. Whilst injury admissions are a subset of emergency admissions, which the applicant already has 's25'1 support for, the applicant wished to make this clear in the protocol, and patient notification documents. For example, adding to the protocol that the applicant will also look at the link between housing characteristics, like presence of stairs, and injury admissions in children, in addition to outcomes already listed.

This amendment also sought support to confirm to CAG that the funding for the study has changed. The study has been funded by NIHR and UKRI-MRC up until this point. The applicant has applied (in a previous amendment) for an extension to 's251' support. This extension will be funded by MRC (until March 2024) followed by HDR-UK.

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

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 21/22 DSPT reviews for **the Office for National Statistics, University College London – School of Life and Medical Sciences & NHS Digital** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 March 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 28 March 2023**

16/CAG/0079 – National clinical audit of breast cancer in older patients (NABCOP)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request
This amendment sought to extend the duration of 's251' support until 30 September 2023. The current contract for the National Clinical Audit of Breast Cancer in Older

Patients (NABCOP) between the Healthcare Quality Improvement Partnership (HQIP) and the Royal College of Surgeons (RCS) of England was due to end on 1 April 2023. This has now been extended by 6 months, until 30 September 2023, via a deed of variation signed by both parties. The NABCOP will be decommissioned after this date, and the audit of breast cancer care in England will be continued by two new clinical audits of both primary breast cancer and metastatic breast cancer in women. Both audits are being run by the RCS of England.

Confidentiality Advisory Group advice

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS England 21/22 DSPT review for **8HM21 – Royal College of Surgeons (RCS) of England** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 March 2023)

20/CAG/0116 – Quality and Outcomes in Oral and Maxillofacial Surgery (QOMS)

Name	Capacity
Ms Clare Sanderson	CAG alternate Vice Chair

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating trusts in England and Wales to the Barts Cancer Care (BCC) Safe Haven Environment, in order for the QOMS project to produce benchmarks for oral and maxillofacial surgery (OMFS) practice and provider-level comparative data for quality of care.

This amendment sought support to expand data capture to not only include head and neck patients treated by oral and maxillofacial surgeons (OMFS), but also head and neck patients treated by other specialties, whose practice overlaps with OMFS, which would primarily include Ear, Nose & Throat (ENT) and Plastics. The applicant has confirmed this would not represent a change to the cohort of patients, as the remits of OMFS and ENT overlap in the area of head and neck cancers, and both specialties treat the same group of patients. This extension to the sources of data would therefore capture more patients with similar conditions to those already reported on.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Alternate Vice-Chair was content to recommend support for this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

Confirmed: The NHS England **21/22** DSPT review for **Barts CR-UK Centre** was confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 16 March 2023).

Due to the number of organisations involved it is the responsibility of Barts Cancer Care (BCC), as controller, to ensure that participating sites where confidential patient information will be accessed meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation

PIAG 4-08(b)/2003 – National Confidentiality Enquiry into Patient Outcome and Death

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes every year. This amendment covered the second of the reviews due to take place in 2022, which will identify and explore areas for improvement in the end of life care of adults with advanced illness. This has been delayed until early 2023 due to the Covid-19 pandemic.

The review has been commissioned as there is believed to be room for improvement in the quality of end of life care. End of life care is relevant to all of us. How it is delivered, however, varies considerably. People frequently do not die in their place of choice, and the quality of care they receive, although sometimes excellent, frequently is not. The population is ageing, and improved treatment of many chronic diseases means that many more people are living longer with these conditions. There will be an

increasing number of deaths where there are limited options for treatment of the underlying condition and death is expected. Excellence in palliative care is therefore becoming of increasing importance.

The applicants aim to publish the results of the review in winter 2024.

Confidentiality Advisory Group advice
The amendment request was considered by Chair's Action. The Vice-Chair agreed that the amendment request was a straightforward amendment for NCEPOD to use its well-established methods to audit End of life care as part of its regular programme, noting it was not an amendment of the methodology, but of the clinical work being audited. The Vice-Chair commented that NCEPOD is very well-established as one of the most effective audits undertaken in the UK, and was content to recommend support.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed – The NHS England 21/22 DSPT review for National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was confirmed as 'Standards Met' on the NHS England DSPT Tracker (by check of the NHS England DSPT Tracker on 16 March 2023)**

3. Amendments – Response to Provisional Outcome

a. ECC 2-03(c)/2012– National Paediatric Diabetes Audit (NPDA)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This is a request to defer the National Data Opt-Out for ECC 2-03(c)/2012. Healthcare Quality Improvement Partnership (HQIP) commission the Royal College of Paediatrics & Child Health, to undertake the National Paediatric Diabetes Audit (NPDA).

NPDA has been collecting data since 2003, and was originally undertaken by the NHS Information centre. Since 2012, RCPCH have undertaken the audit, under 's251' support, with consistent submission of annual reviews since that time.

NPDA has existing support to collect confidential patient information on children and young people treated for diabetes. Support is also in place to link to NHS Digital outcome data.

Confidentiality Advisory Group advice

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

1. **Further information is required to evidence that application of the National Data Opt-Out would have an adverse effect on patient safety, and health inequalities. This should include more detail on the examples provided in the meeting, and further examples.**

The applicant initially provided one further example regarding how benchmarking for local services specifically reports on percentages of ethnic minority children and young people using diabetes related technologies, by ethnic group and deprivation quintile. Because there are such small numbers initially, this limits the amount of useful data that can be published already, due to the ICO guidance on the reporting of small numbers. As there is evidence that a higher proportion of ethnic minority

children would potentially opt out via the NDO, if the NDO were to be applied, it would drastically change the usefulness of this important output, as this would further reduce the amount of services that this specific report could be published for. This would mean that services would not be able to reduce health inequalities with regards to access to diabetes related technologies, as they would not be aware of any issue.

In addition, the applicants used data from another audit that found 20% of babies born to mothers of black ethnicity had data missing due to the application of the NDO, which is far higher than average. Using this data, the applicants modelled what would happen regarding adjusted HbA1c outlier analysis if 20% children and young people of black ethnicity were removed from the cohort. Applicants found that despite only 4.1% of the total cohort being of black ethnicity, reducing this by a potential 20% meant that one less service was identified as an outlier, and 2 services changed status between the initial and revised analysis. This could compromise the safety of patients treated in the future, including both those who have opted out and those who haven't.

The CAG requested further information, as it was felt that more examples would further justify the audit being exempt from the NDO. The applicant provided further information to CAG in February 2022. The applicant explained that applying the NDO to the NPDA would lead to a deterioration in diabetes care for a child or young person with diabetes, and as such severely impact patient safety. An example was provided, showing that Individual Paediatric Diabetes Units (PDUs) would lose their current ability to track effectively the key annual health checks focused on by the NPDA, which are important to undertake so that problems related to diabetes can be identified at an early stage, and advice and any appropriate related treatments can be provided. This is because from the audit data, there is a correlation between outcome and engagement with a PDU - i.e. blood glucose control is better with increasing engagement. The year-on-year improvement in engagement is a consequence of PDUs being able to benchmark their numbers longitudinally. Applying the NDO is likely to destroy this sequential monitoring leading to a reduction in the safety and health outcomes of children and young people with diabetes, particularly in vulnerable groups living in the most deprived areas and for children and young people of ethnic minority status.

The applicant also provided evidence to show that deterioration in care and/or poor interaction with health care teams massively increases the chance of a child or young person suffering complications from the disease including blindness, kidney failure requiring dialysis and/or renal transplant, vascular disease leading to limb amputations, heart attacks and strokes at a much younger age than the general

population. The current methodology used by the NPDA over the last 10 years, where every child with diabetes under the care of PDUs across England and Wales is included, has led to a reduction in these risks by at least 40%. These improvements can only be demonstrated by complete ascertainment in the audit. The NDO is likely to have a larger than average influence on the less engaged families, those living in more deprived areas and ethnic minorities. Therefore, it is highly likely that any loss in data due to the NDO will skew NPDA data analysis and lose the influence it has had to date on patient safety and improved outcomes over the last 10 years.

The NPDA provides PDUs with the ability to monitor whether a particular child may be missing any or all of the required key health checks via the NPDA Data Completeness Report (DCR). The DCR is generated each time that a PDU uploads data to the NPDA system. It gives an indication, at a patient and service level, of the completion rates of care process, outcomes achieved, and characteristics of those using the services provided by a PDU. PDUs can use the DCR to check various metrics. Any unexpected results shown via the NPDA DCR will alert PDUs to missing, incomplete or incorrectly entered data. Applying the NDO to the audit would remove those children and young people affected from the related PDU's data on the NPDA DCR and the important patient safety functionality described above that it provides. This is further explored below.

The applicant also put forward a more comprehensive argument explaining why the application of the NDO would adversely affect health inequalities. This was explained in November in less detail, however has been explained further in the February response. The NPDA has, in its most recent annual reports, already identified that inequalities exist and persist in relation to the use of such diabetes related technologies by ethnic groups and deprivation quintiles, with Black children and young people least likely to be using this technology. Usage of such technology is highly associated with improved outcomes. Barriers to achieving excellent outcomes amongst those children and young people living in more deprived areas and of Black ethnicity must be identified and mitigated to ensure significant overall national progress in addressing these inequalities. It is likely that applying the NDO to the NPDA will affect these groups unequally and lead to a further demise in their healthcare and safety with regards to long-term complications.

The ability of the NPDA to continue to comprehensively benchmark the use of diabetes technologies by ethnic minority children and the associated continued health inequalities and patient safety risks, would very likely be adversely impacted by the application of the NDO to the audit. The applicant explained that a key reason for this is that there are already relatively small numbers of children and young people from of an ethnic minority background, whose data are processed through the audit and due to evidence suggesting that a higher proportion of ethnic minority children and/or their parents opt out via the NDO, that would further reduce the ability of the NPDA to

appropriately and comprehensively analyse and report representatively on behalf of these children and young people. Even where (incomplete and non-representative) analysis might still be possible at a national level, if the audit were subject to the NDO, the small numbers within certain networks or PDUs might result in the data being suppressed in reporting, in order to mitigate against a possible data disclosure risk to individuals. This would in turn affect patient safety as, if benchmarking cannot be reported accurately, then it will not be known where problems persist and improvements need to be made regarding the use of diabetes technologies by children of an ethnic minority, thus further increasing health inequalities. This would impact adversely not just on those who have opted out via the NDO, but also those who have not opted out via the NDO.

The CAG thanked the applicant for these further clarifications, and agreed that the application of the NDO to this audit would create a serious safety risk to patients. The CAG were content that the NPDA supports patient safety in the NHS by monitoring the performance of paediatric diabetes services against the national guidelines, and helping Trusts assure the safety and standards of their services. Excluding data from patients who have opted out via the NDO could compromise the mechanisms and safeguards that protect the safe care of these patients and that of non-NDO patients. As the only quality focused dataset collecting information on paediatric diabetes services, the NPDA provides a platform for knowledge sharing, and promotes local and regional quality improvement. These functions are dependent on complete high-quality data collected by the audit on patient care and service provision. Excluding data from NDO patients reduces the quality and quantity of data available for services to monitor and improve the care they provide.

Examples provided include benchmarking performance against other services and national standards. If NDO patient data has to be excluded when calculating these results, applicants cannot accurately determine if Trusts have sufficient provision of paediatric diabetes services and whether all children with diabetes are receiving equal levels of support and provision. There is therefore an increased risk of patients being treated by a service that doesn't have the necessary data to accurately ascertain whether it is maintaining the quality of paediatric diabetes services that it provides, for example one where key professionals are not providing care in line with NICE guidance and quality standards, which would adversely impact patient safety. This risks the safety of individual and collective patients, as services could miss opportunities to improve care for an individual child and also not have the appropriate information to identify areas for improvement and learn from previous experiences to assure safety and standards in future.

The CAG agreed that the audit covers accurate data collection on children and young people with diabetes, including demographic and ethnicity factors, a checklist of services and advice that should be offered to qualifying patients, and a series of

indicators about individual professional performance and Trust performance which are there to support high standards of care based on best practice evidence. The CAG stated that parents or patients who might have registered an NDO may be unaware that they will be excluded from this audit, and therefore may miss out on the range of services and advice that is prompted by the audit which could have safety implications for individual patients. The audit monitors both individual clinician performance and Trust performance which could become inaccurate with serious consequences of error in either direction, for example failure to recognise good performance or poor performance if the NDO is applied due to missing data.

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

2. **Please provide further clarification/confirmation surrounding the number of Trusts which use the NPDA database as a clinical follow up tool, in place of their own EPR, so CAG can be clear to what extent the NPDA is used as a tool for ensuring key health checks are made, and if application of the NDO would affect individual patient care. Please also describe how patients who opt out locally are clinically managed, and how their care is affected by not being on the NPDA database.**

The applicants completed a survey to confirm the proportion of Trusts using the NPDA as a clinical tool. Overall, the majority (57.1%) were using the tool to track individual patients healthcare. In order to answer the query from CAG, applicants spoke in detail to one of the sites that were using the NPDA database as a clinical tool, and who also had opted out patients. This site explained they also use a secondary clinical tool, and all patients are cross checked across both tools. The site also explained that they had managed to gain consent from 3 of the NDO opted out patients, in order to include them in the audit. The CAG were content with this response, and from the percentage of sites using the NPDA as a clinical tool, it is clear that the safety of NDO patients who are not entered onto the data capture platform could be at risk, as the NPDA data platform acts as a clinical tool to ensure children and young people receive recommended care.

3. **Please consider if it is possible for a consent option to be built in to the audit, which would override the NDO. This can be addressed further as part of the resubmission.**

The applicant has stated that since 2012 it has been agreed that it would be impractical to ask for consent for the NPDA, as the number of patients means this would create a

large burden on the clinical team, as the time taken to appropriately consent a patient is not available as part of the clinical appointment. The CAG stated that the arguments made were reasonable, but agreed this should be revisited and the arguments remade at the point of the refreshed submission to CAG.

4. **Please provide updated patient notification methods, which make it clearer how an individuals can opt out of NPDA only. Please also develop child and young person friendly materials.**

The applicant has developed these as requested. The CAG were content to recommend support on the basis of the documents provided, however the Members commented on the complexity of the patient-facing information. The applicant is to consider creating a shorter, simpler notification, that links on to this detailed version should be provided as part of the resubmission, as suggested by the ICO layered approach to information provision.

5. **Please provide evidence of discussions with patients and the public, including children, surrounding the non-application of the National Data Opt-Out. Feedback from this activity needs to be provided to the CAG.**

The applicant confirmed that the Audits Team within the RCPCH has undertaken a number of engagement activities with children, young people, parents and carers. Across October and November, over 20 children were spoken to at 5 separate diabetes clinics by RCPCH. These communications were undertaken as 1:1 conversations, and other questions about the NPDA were also asked, in an age appropriate manner. The children were asked for their views on the National Data Opt Out (NDO) process. There was a consensus that the NPDA data is a powerful tool used to improve services and quality of care, and this should continue as long as published data is anonymised and information around the audit, the NDO and how to withdraw from NPDA specifically is clearly communicated to patients and families. The CAG accepted this response.

Confidentiality Advisory Group advice conclusion

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

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

Specific conditions of support

The following sets out the specific conditions of support.

1. This outcome confirms a change to the original conditions of support. The National Data Opt-Out is not to be applied to patients included in the activities specified in ECC 2-03(c)/2012.

2. A local patient objection mechanism must continue to be used in relation to ECC 2-03(c)/2012.

3. This NDO exemption does not apply to research application 18/CAG/0002.

4. The applicant is requested to submit a refreshed new application to CAG. This was initially requested in lieu of their next annual review (15th November 2022), however this is now requested in lieu of the next annual review, which is 15th November 2023, or prior. This new application will supersede ECC 2-03(c)/2012, and the applicant is to provide updated simpler information sheets that lead on to the more complex ones provided, as part of the resubmission.

4. Annual Review Approvals

22/CAG/0014	The Trauma Audit & Research Network (TARN)
17/CAG/0018	Implementation of a Telephone-Based Case Management Intervention for Patients at risk of High Emergency Department Utilisation in the English NHS
17/CAG/0184	UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)
CAG 9-08(b)/2013	Linkage of readmissions to birth data
21/CAG/0007	National Neonatal Audit Programme (NNAP) data flow
18/CAG/0184	Using National Congenital Heart Diseases Audit data to explore the impact of non-medical risk factors on late post-operative outcomes for children with complex congenital heart defects.

22/CAG/0042	A long-term prospective cohort study on the effects of smoking and prophylactic aspirin on all-cause mortality in male British doctors
22/CAG/0007	Prison healthcare, focusing on natural and other non-natural deaths
19/CAG/0115	Suspected Stroke Clinical and radiological data base (SSCRaD)
19/CAG/0001	National Asthma and COPD Audit Programme (NACAP): Children and young people (CYP) Asthma Clinical Audit
22/CAG/0012	Using linked secondary and primary care electronic health records to evaluate opioid utilisation and safety
17/CAG/0033	prospective observational study of the long term hazards of antiTNF therapy in rheumatoid arthritis
21/CAG/0132	Evaluating the health inequality effects of the Best Practice Tariff for hip fracture
21/CAG/0121	Long-term risk of cancer and general health outcomes in women who underwent assisted reproductive technology in Great Britain, 1991-2010: a data linkage study
20/CAG/0028	Small Area Health Statistics Unit Research Database

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Dr Murat Soncul & Professor William Bernal, CAG Alternate Vice-Chairs	*24 April 2023*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*18 April 2023*