Minutes of the meeting of the Confidentiality Advisory Group

16 February 2023 via Zoom

Present:

Name	Role
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	Vice Chair
Dr Sandra Duggan	CAG Member
Mr David Evans	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Andrew Melville	CAG Member
Professor Sara Randall	CAG Member
Mr Dan Roulstone	CAG Member
Mr Marc Taylor	CAG Member

Also, in attendance:

Name	Position (or reason for attending)
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Mr William Lyse	HRA Approvals Administrator
George Dunn	NMPA Lead (item 3a only)
Tina Harris	NMPA Senior Clinical Lead (item 3a only)
Alissa Harvey	NMPA Statistician (item 3a only)
Kelly Rowe	HRA Approvals Manager (Internal observer)
Thomas Boby	CAG Member (Observer)
Sarah Palmer - Edwards	CAG Member (Observer)

1. Introduction, apologies, and declarations of interest

There was no declaration of interest raised within the CAG meeting.

2. Support decisions

Apologies from: Dr Rachel Knowles, Ms Clare Sanderson (AVC)

Secretary of State for Health & Social Care Decisions

No non-research applications were discussed at the **19 January 2023** CAG meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **19 January 2023** meeting applications.

Minutes:

Published 13 January 2023 Precedent Set

3. National Data Opt-Out Deferral

a. 16/CAG/0058 - National Maternity and Perinatal Audit (NMPA)

Scope of NDO deferral request

The applicants have existing support to allow the disclosure of confidential patient information from English & Welsh NHS Trusts to the Royal College of Obstetricians and Gynaecologists, and to link this data with data contained in other national databases for the purpose of conducting a national, prospective, clinical audit of maternity services in England and Wales, in order to improve the quality of services and the outcomes achieved for mothers and new-borns.

Confidentiality Advisory Group advice

The applicants provided a cover paper, which set out their rationale as to why the NDO will significantly impact the audit.

1. Deferral rationale: patient safety

The applicants noted concerns that the loss of data resulting from application of the National Data Opt-Out would lead to bias and make it difficult to compare data across trusts. The impact on patient safety would not be uniform across all patients.

The NMPA Ethnic and Socio-economic Inequalities report has shown that there is variation in maternal and neonatal outcomes based on ethnicity and level of socio-economic deprivation and it is therefore plausible that those at greatest risk of adverse outcomes associated with socioeconomic and ethnic inequalities would be disproportionately affected by loss of data from the NDOO.

The NMPA is a national audit which endeavours to provide reliable national, trust and site level data to clinicians and healthcare professionals who can use these data to make decisions which impact patient safety. If these data are no longer

representative of a national picture, but are of a select percentage of women and birthing people, varying not uniformly by several factors include age and location, this would put in doubt the decisions made based on NMPA data.

Members noted that maternity services in several parts of England have been recognised as poor performers with very significant patient safety concerns identified. The Group was concerned that the audit process should obtain as complete a dataset as possible to enable that Trust management and Regulatory bodies have the most complete information available to address these concerns. The CAG agreed that there was a strong patient safety argument for deferral of application of the National Data Opt-Out.

2. Deferral rationale: Introduction of bias

The applicants noted a risk of selection bias, due to the non-uniform loss of patients.

Processes and outcomes in maternity care are socially patterned. Application of the NDOO has been found to differ demographically, geographically, and socio-economically. When the loss of data differs, the NMPA's ability to make generalisable recommendations is weakened.

The applicants provided statistics on how application of the NDOO varied across GP practices and regions, and by age. The CAG noted that MMBRACE UK, which had been granted deferral of application of the NDOO, had made similar arguments around geographic and demographic differences in take up of the NDOO and geographic and demographic variations in mortality.

Informing the patient population

Currently the NMPA has a section of the FAQs dedicated to Information Governance and data access, which functions as the NMPA Fair Processing Notice. This information included a statement on the NMPA exemption from the National Data Opt-Out. Should this application for exemption from the NDOO be successful, the NMPA fair processing notice will be updated to ensure that participating Trusts, mothers, birthing people and the public are informed of the exemption.

The exemption will also be explained in the 'Family Gateway' area of the NMPA website. Should the application be successful, guidance on the opt-out will be explained here, with the wording co-produced with the Women and Families Involvement Group (WFIG) to explain the decision. The NMPA quarterly newsletter will also contain information about the exemption.

The CAG agreed that a clearer explanation of the project-specific opt-out needed to be communicated to patients. The exemption to application of the National Data Opt-Out also needed to be explained.

Patient and public involvement and engagement

The applications noted that exemption to applying the National Data Opt-Out had been granted to similar audits and surveillance systems, such as the National Neonatal Audit Programme (NNAP) and MBRRACE-UK. Whilst the NMPA's audit role is distinct from the surveillance conducted by NNAP and MBRRACE-UK, NDOO exemption will increase comparability between the findings of these three organisations, strengthening the ability to improve quality of maternity care.

The applicants had conducted a consultation about the impact of applying the NDOO with members of the Women and Families Involvement Group (WFIG). 10 members of the WFIG were consulted. The WFIG were supportive of exemption being granted. Examples of the feedback given are included in the cover paper.

The CAG agreed that further details were needed on the diversity of the patient and public involvement group. When invited into the meeting, the applicants advised that the PPI group was less diverse than would be ideal and were taking steps to increase the diversity.

The CAG also noted the importance of discussing the application and deferral of the NDOO with patients who had registered with the NDOO, in order to explain the application activity and the importance of the audit. The applicants agreed that this patient group would potentially be hard to reach but noted the usefulness of explaining the specific use of data for this application and that all analysis was undertaken on anonymised data. The CAG recognised that consulting this patient group may be difficult and asked the applicants to explore the feasibility of undertaking this consultation and seek to consult relevant patients, if possible.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a strong public safety element in exploring maternity and perinatal care.

The CAG agreed that they were supportive, in this specific instance, of the request for the application of the National Data Opt-Out to be disapplied in relation to the non-research activities contained within 16/CAG/0058. The CAG therefore recommended to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be conditionally approved.

Specific conditions of support

1. The patient notification materials need to be revised to contain a clear explanation of the project-specific opt-out and the exemption to application of the

National Data Opt-Out. These materials are to be provided within 3 months of the issuing of this letter.

2. Further patient and public involvement needs to be undertaken and reported on within 6 months of the issuing of this outcome letter. This needs to include:

    a. Discussion of how confidential patient information is used in this application and the reason for deferring application of the National Data Opt-Out.

    b. A more diverse group of patients needs to be involved.

    c. The feasibility of consulting patients who have registered a National Data Opt-Out to explain the application activity and the importance of the audit needs to be explored and seek to consult relevant patients, if possible.

3. The National Data Opt-Out is not to be applied to patients included in the activities specified in 16/CAG/0058.

4. A local patient objection mechanism must continue to be used in relation to 16/CAG/0058.

4. New Applications

a. 23/CAG/0020 - Behaviours predicting CPAP adherence in OSA: a modelling analysis

Purpose of application

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

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

The applicants have already collected data from remote monitoring of CPAP devices for five centres. The applicants require support to process confidential patient information for patients treated by Wythenshawe Hospital, part of Manchester University NHS Foundation Trust, to collect data for a validation cohort. A consecutive list of 100 patients will be extracted from the Airview database for Wythenshawe Hospital, Manchester University NHS Foundation Trust, from 2019, avoiding patients used for the previous analysis. Each individual patient will be checked for eligibility and patients excluded as necessary. CPAP-usage datafiles will be downloaded for each patient at each of the relevant time points over three months

and recorded in the results database under a code number. The relevant clinical data obtained from the electronic patient records system will be recorded in the results database. The process will be continued until data from 100 patients is collected. The process will be repeated for a second patient sample treated in 2021 and therefore treated under a different clinical pathway. This database and the pre-existing database of 1000 patients, both pseudo-anonymised, will be transferred to the statistician.

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

Confidential patient information requested

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

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

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The applicants had confirmed that support under s251 was only required to process confidential patient information from Manchester University NHS Foundation Trust for the validation cohort. The data already collected from remote monitoring of CPAP devices for five centres had already been undertaken with service evaluation and audit as the legal basis. The CAG agreed that, as this data had already been collected, it was not included in the scope of support.

The CAG requested clarification regarding the number of patients that would be included under the scope of support. 200 patients were referred to in response to some of the questions within the CAG application form and 100 patients were referred to elsewhere. The CAG noted that it appeared that 100 patients each would be included from two clinical pathways making 200 patients in total. Confirmation that this understanding is correct is needed.

Practicable alternatives

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

- **Feasibility of consent**

The applicants advised that consent was not feasible due to the risk of bias. Patients who do not adhere to CPAP therapy are more likely to avoid contact with sleep teams than those who are complying.

The CAG highlighted that the applicants were planning to use retrospective data for this study and that patients were already being asked to consent to monitoring of data from devices. Members queried whether data could be collected prospectively for patients who had not yet received treatment. The patients could be consented into the trial when commencing treatment and their data collected, removing the need for s251 support

- **Use of anonymised/pseudonymised data**

The applicants require access to confidential patient information without consent to identify eligible patients and extract their data.

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

'Patient Notification' and mechanism for managing dissent

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

The CAG underlined the fact that no patient notification was provided for review. The CAG requested that the applicants create patient notification materials and a mechanism for patients to dissent to use of their data. Members stated that contacting each participant separately was not required and that a simple poster or leaflet would be sufficient and for these to be displayed at relevant clinics and websites. This notification should provide a description of the purpose of the study as well as information on the research team. Lastly, the notification should explain the local opt-out mechanism. The CAG usually expects that telephone, email and postal contact details are provided, should patients have queries or wish to dissent to the inclusion of their data. The National Data Opt-Out also needed to be applied.

Patient and Public Involvement and Engagement

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

The applicants had conducted focus groups for two other CPAP related projects with 41 patients diagnosed with OSA. The applicants advised that they had briefly discussed the use of retrospective CPAP data without consent. Those consulted were supportive.

The CAG requested for the applicant to clarify whether the patient and public interest group discussed the use of confidential patient information without consent, as proposed within this application

The CAG noted that the applicants had stated that patients who did not comply with CPAP treatment may also object to use of their data in research. Members queried whether this was correct, noting that patients may find the treatment inconvenient or ineffective while still supporting the need for more research evidence about their experience of the treatment being explored. The CAG requested that the applicant discuss with the patient and public involvement group how they can notify those who no longer comply with CPAP with the research and the use of confidential patient information without consent.

Exit strategy

Confidential patient information in the CPAP-usage files will be downloaded. The data will be extracted, and a code number applied. Once the patient's age, gender, and other relevant information for their OSA diagnosis is taken from their hospital records and entered into the database, which takes another 10 minutes, there is no further need for patient identifiable data. The data will be pseudonymised. Only the chief investigator and the researcher collecting the research data will have access to the pseudonymisation key. Once the data has been accepted for publication and will no longer need to be checked, the pseudonymisation codes will be changed to anonymised codes in the research database (e.g. to simple consecutive number order) and the “key database” destroyed.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

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

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

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

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

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

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

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

Specific conditions of support (provisional)

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

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

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

   The NHS Digital **21/22** DSPT reviews for **Manchester University NHS Foundation Trust** and **Imperial College London** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 17 February 2023)

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

Purpose of application

This application from National Perinatal Epidemiology Unit, University of Oxford set out the purpose of creating a research database containing data relating to children treated

for necrotising enterocolitis (NEC), Hirschsprung's disease (HD), gastroschisis, posterior urethral valves (PUV), congenital diaphragmatic hernia (CDH) and oesophageal atresia (OA).

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

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

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

Confidential patient information requested

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

Cohort	Children diagnosed with any of the following six conditions: 1.Hirschsprung's disease 2.Oesophageal atresia

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

Confidentiality Advisory Group advice

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

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose

within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application was strongly in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

The applicants advised that consent was not feasible due to the low numbers of patients receiving specialised surgery. The incidence of most of these conditions in the UK is around 1:5000, translating to approximately 150 infants live born with each condition per year. With 28 hospitals providing specialised surgery for children in the UK, there are roughly 5 children treated with each condition per hospital per year. This meant it was important to obtain data for as many patients as possible.

It would not be feasible for staff within the departments providing specialised surgery to seek consent due to lack of resources.

The CAG noted the applicant's argument on why consent could not be sought for this study. However, members noted that a small number of patients would be recruited from each participating unit. Patients would also be in hospital for a significant amount of time, providing opportunities for the register to be explained and consent sought.

The CAG also noted that case ascertainment had also been given as a reason for not seeking consent. However, not every unit that undertook the relevant procedures would be participating, therefore case ascertainment was not complete.

The CAG requested that further, concise reasons were provided on why consent could not be sought by the NHS staff, during the patients' clinical visits and hospital stay, and the impact on the statistical analysis should all patients treated at the participating units not be included.

- **Use of anonymised/pseudonymised data**

Confidential patient information is needed in order to link patient level data from the Electronic Patient Records at participating trusts to the HES dataset at NHS England.

Confidential patient information is also required to facilitate the applicant's contact with patients or their parents/carers to seek consent for collection of quality of fife data via questionnaires.

The CAG was content that using anonymous information was not a practicable alternative.

‘Patient Notification’ and mechanism for managing dissent

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

The applicants provided a poster. This will be displayed at participating trusts. Information about the CSOR will also be made available on the CSOR webpages and written information will be provided at participating sites.

Parents will be able to dissent to use of their child’s data in the unconsented data collection process by emailing or calling the CSOR Research Database team. Email and telephone contacts were provided. The CAG asked that a postal contact was also included.

Where parents register their dissent, the CSOR Research Database team will request from the parents their child’s NHS number, name and date of birth. The CSOR research database team will then inform (via secure NHS email) the lead clinician at the child’s treating site, as well as the lead member of staff in the informatics team responsible for providing the unconsented data from that site, of the parent’s dissent. Mechanisms for registering dissent locally will vary from site-to-site dependent upon the electronic patient records system they use, however, this will likely mirror the mechanisms in place for preventing data flows if a patient has completed the National Data Opt-Out.

The applicants provided the text to be included on the CSOR website. This didn’t explain how confidential patient information could be used without consent and how patients/parents could dissent. The CAG asked that the website text was revised to describe how patient data would be used and how patients or their parents could dissent.

NHS England will apply the National Data Opt-Out.

Patient and Public Involvement and Engagement

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

The study team at the University of Oxford had set up the Parental Advisory Group (PAG) to aid in developing the CSOR programme. The PAG consists of over 100 parents and families of children with surgical conditions, as well as representatives from charities and support groups. Annual meetings have been held to update, discuss and collect feedback on the CSOR programme. Feedback from the PAG has been key to the development of the proposed parent consent and data collection process.

The issue of use of confidential patient information without consent has been discussed with the PAG. The PAG was in favour of this approach, as long as information about the research was made available and the results of the research were also publicised.

Two parent or patient representatives will be included on the CSOR Research Database Steering Committee to ensure that the parent/patient voice is maintained in the functioning of the CSOR Research Database. The CSOR Research Database will continue to be reviewed at the annual PAG meeting.

The CAG noted the exceptional use of patient and public involvement within this application.

Exit strategy

Only the CSOR database programmer will have access to the pseudonymisation key. It will be held at Oxford University Hospitals NHS Foundation Trust. We have been advised that the information transferred to the University of Oxford should be considered pseudonymised because of the existence of this key, even though it is not held at the University of Oxford.

The CAG was satisfied with the proposed exit strategy for this application.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

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

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

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

Specific conditions of support (provisional)

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

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

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

Due to the number of NHS Trusts involved, it is the responsibility of NHS England, as controller, to ensure that NHS Trusts meet the minimum required standard in complying with DSPTs and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a Trust.

5. Any other business

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

Signed – Chair	Date
Dr Tony Calland MBE	21/02/2023
Dr Patrick Coyle	22/02/2023

Signed – Confidentiality Advice Team	Date
William Lyse	09/03/2023