Minutes of the meeting of the Confidentiality Advisory Group

17 June 2021 – held via zoom

Present:

Professor William Bernal	CAG alternative vice-chair
Mr David Evans	CAG member
Professor Lorna Fraser	CAG member
Mr. Myer Glickman OBE	CAG member
Dr Katie Harron	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Harvey Marcovitch	CAG member
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Ms Diana Robbins	CAG member
Mr Umar Sabat	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Laura Gordon	HRA Confidentiality Advisory Group Assistant
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Emma Marshall	HRA Observer

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

No non-research applications were considered at the **20 May 2021** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **20 May 2021** meeting applications.

3. New applications – Research

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

Context

Purpose of application

This application from the Neonatal Data Analysis Unit (NDAU) at Imperial College London sets out the purpose of medical research that aims to improve the lifelong health and wellbeing of babies born preterm and/or with surgical conditions by linking existing data from the National Neonatal Research Database (NNRD) with routine health, educational and environmental datasets in England and Wales to evaluate the long-term impact of neonatal interventions. A pseudonymous linked dataset will be crated for analysis, and the applicant is specifically researching long-term health and educational outcomes, the effect of air pollution or other environmental and socio-economic factors, and the impact of neonatal interventions, for example donor breast milk, on health and educational outcomes.

Medical and surgical interventions in babies born preterm and/or with surgical conditions influence health and educational outcomes. Survivors are at risk of long-term neurological impairment and ongoing health, educational and social care needs, however due to the cost and complexity of obtaining long-term outcome data mean that longer term outcomes for the 90,000 babies born very preterm in the UK over the last decade is not yet known. This research will benefit children born preterm and/or with surgical conditions by identifying modifiable factors that influence long-term health and developmental outcomes, with the aim of improving outcomes for this patient group. Information on long-term outcomes will support counselling of families, decision-making, and inform future research and public policies to benefit patients and families.

Support is requested to use confidential patient information held in the NNRD for the purpose of linkage, by three trusted third parties – NHS Digital, Digital Health & Care Wales (DHCW) (Formerly known as NHS Wales Informatics Service, NWIS) and Office for National Statistics secure research service (ONS-SRS). These third parties will remove identifying information, and disclose only outcome data alongside an anonymised unique ID. The researchers will not have access to any confidential patient information and no individual patient will be able to be identified. A split file process will be used which will ensure that no organisation will hold identifiers along with clinical data together.

Four cohorts of babies born between 2007 and 2020 who are either preterm, and/or have a surgical condition, will be created from the NNRD. The NNRD is an established

national database retaining confidential patient information which is collected with support under the Regulations as the legal basis (CAG ref: **ECC 8-05(f) / 2010**). These cohorts will be linked to other health and education databases. A unique ID will be applied by the NDAU.

Regarding Welsh data, NDAU will disclose identifiers from NNRD to DHCW (formerly NWIS) in a 'File 1', as Trusted third party for purposes of linkage with Welsh data in SAIL databank. Linkage with SAIL data is undertaken by DHCW without identifiers and this therefore does not require Regulation 5 support. 'File 2' of NNRD clinical data only, alongside the unique ID is disclosed to SAIL from the NDAU, and will be linked to Welsh health and education outcome data using only the anonymised unique ID.

For English data, PICANet, South London and Maudsley Clinical Record Interactive Search (SLaM-CRIS), and NDAU will send the identifiers (file 1 - NHS number, sex, postcode, date of birth, unique ID) for babies born in the study years to NHS digital as the trusted third party. Note that not all the NNRD records will have a match in the PICANet and CRIS datasets, and multiple PICANet or CRIS records may match with same record in the NNRD. NHS Digital will only retain PICANet and CRIS records that match with NNRD, non-matching identifiers will be discarded. (Note that NDAU will not be sending identifiers directly to PICANet / CRIS as a large proportion of these identifiers will not have matches).

NHS Digital will undertake linkage between the NNRD cohorts, PICANet, CRIS, HES, ONS mortality data, and MHSDS. Identifying information is then removed, except the unique ID, and the pseudonymous dataset is transferred back to the NDAU. File 2 from each source (clinical data, unique ID, no identifiers) is then linked back to the outcome dataset from NHS Digital using the unique ID only by the NDAU.

Regarding English education data, the Department for Education (DfE) holds the National Pupil Database (NPD) in the ONS-SRS and data from the NPD cannot leave the ONS SRS. The NNRD reliably captures data items such as date of birth, postcode, and infant NHS number, but it does not reliably hold the child's registered name. Additionally, the NNRD contains the infants' postcodes at birth, but does not capture postcode changes throughout childhood. Therefore NHS Digital will also link the identifiers from the NNRD cohorts to the Personal Demographics Service (PDS) to identify registered forename and surname and postcode changes, in order to undertake linkage with the NPD which does not contain NHS number. Forename, surname, date of birth, and postcodes alongside unique ID will be securely transferred to the ONS SRS to be used to link to educational data within the NPD. Identifying information is then removed. The NDAU send the clinical NNRD-HES/ONS/MSDS-PICANet-CRIS data and unique ID to ONS SRS and this is then linked to NPD using unique ID. The final de-identified NNRD-HES/ONS/MSDS-PICANet-CRIS-NPD linked dataset (without

identifiers) will be accessed via researchers in the ONS-SRS safehaven, and the de-identified linked Welsh data will be accessed within the SAIL databank.

A recommendation for class 1, 2, 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	Approximately 120,000 babies born and received care in neonatal units in England and Wales between 1st Jan 2007 and 31st December 2020; recorded gestational age of less than 32 weeks **OR** Any gestational age AND recorded to have received surgery and diagnosis of one of 6 conditions: necrotising enterocolitis, Hirschsprung's disease, gastroschisis, oesophageal atresia, congenital diaphragmatic hernia and posterior urethral valves. 1. **Cohort 1 Born 2007-2020 in England: link to health data (HES,ONS, PICANet, MHSDS)** Preterm babies born less than 32 weeks and surgical babies (all gestations) 2. **Cohort 2 Born 2007-2016 in England: link to school age outcomes (NPD and CRIS)** Preterm babies born less than 32 weeks gestation 3. **Cohort 3 Born 2012-2016 in England: link to school-age outcomes (NPD and CRIS)** Surgical babies (all gestations) 4. **Cohort 4 Born 2012-2020 in Wales: link to SAIL databank (contains health, education, social data)**

	Preterm babies born less than 32 weeks (Inclusion criteria: Preterm babies born <32 weeks in neonatal units in Wales 2012-2019 (11 neonatal units in the Wales Neonatal Network))
Data sources	1. National Neonatal Research Database controlled by the Neonatal Data Analysis Unit (NDAU) (Chelsea and Westminster NHS Foundation Trust campus of Imperial College London) 2. NHS Digital • NHS Digital Personal Demographics Service (PDS) • Hospital Episode Statistics (HES) • Office for National Statistics (ONS) mortality data Identifiers include NHS number, date of birth, gender. • Mental Health Services Dataset (MHSDS) **(**The MHSDS also contains its predecessor, the Mental Health and Learning Disabilities Data Set and the Mental Health Minimum Data Set) 3. National Pupil Database (controlled by Department for Education DfE), retained in the ONS-SRS 4. Paediatric Intensive Care and Audit network, (PICANet) controlled by Healthcare Quality Improvement Partnership (HQIP) and is retained at the Universities of Leeds and Leicester 5. South London and Maudsley Clinical Record Interactive Search (SLaM-CRIS); held and controlled by South London and Maudsley NHS Foundation Trust (SLaM) at King's College London. 6. (SAIL) databank, also holds education data for Wales. (linkage is undertaken by using DHCW (formerly NWIS) as a trusted third party without using confidential patient information and support not required).

Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Sex 4. Postcode 5. Unique ID
Identifiers required for analysis purposes	6. N/A no identifiable information for analysis
Additional information	**Date of death:** Note that date of death is modified to postnatal age at death by NHS Digital **Data access:** The de-identified linked dataset set containing education data will be accessed through the Office for National Statistics (ONS) Secure Research Service (SRS). A de-identified dataset without the education data will also be held on the Imperial College server. A de-identified linked Welsh dataset will be retained in SAIL databank.

Confidentiality Advisory Group advice

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

Public interest

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

The Members were very supportive of this application, noting the clear medical purpose and the strong public interest, acknowledging that this appeared to cover a major gap in current knowledge.

Practicable alternatives

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

- Feasibility of consent

The applicant has reasoned that consent is not feasible for a number of reasons, including the further disclosure of address required in order to contact families to seek consent, the possibility of compromising the integrity, generalisability, validity and representativeness of the study, the potential distress it may cause to families of children with who may have severe disabilities or who may have died, and the large numbers of children involved would make consent prohibitive. The CAG agreed with the justification provided that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is required to undertake linkage. Linkage will be conducted using a split-file process. Identifiers will not be held alongside clinical or educational outcome data. The minimum number of personal identifiers will be used for linkage. These will associated with a unique anonymous identifier ID number. Upon confirmation of linkage, all personal identifiers will be removed, and the clinical and educational data pseudonymised - retaining the anonymous unique identifier. The Members agreed it would not be possible to undertake linkage in any less disclosive manner, and the proposed data flows appeared safe and comprehensive.

Justification for Slam-CRIS

Members commented that they were unclear why the applicant required SLaM-CRIS data, as this is a very small, distinct population in one area of London, and the applicant is already receiving data from the Mental Health Services Dataset (MHSDS) from NHS Digital. The applicant is requested to provide further justification for the inclusion of SLaM-CRIS data.

'Patient Notification' and mechanism for managing dissent

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

A patient notification has been provided for review. It will be disseminated through stakeholder groups including collaborator BLISS, a national charity for preterm and sick

babies, networks of the neoWONDER parent/patient group (around 400 people), and social media platforms of other charities such as Smallest things, and Twins Trust. The applicant also states it will be disseminated to parent/patient preterm groups, out-patient clinics, community clinics, charities, and schools to raise awareness of the study and offer the chance to opt out. It will be also be displayed on the neoWONDER website as well as social media (Facebook, Instagram and twitter). Applicants are connecting with schools and SENCOs (Special Educational Needs Co-Ordinators), to raise awareness. They are also developing a 1 minute video for the the neoWONDER website and you tube.

A Letter has also been provided which is sent to neonatal units that participate in NNRD. To access data available in the NNRD, all neonatal units will be written to with information about the study and offered the opportunity to opt-out (as a whole unit). This is an established process managed by the Neonatal Data Analysis Unit (NDAU) based at Imperial College, and is a standard process for researchers who wish to use NNRD data.

A local opt out option is provided, for parents or carers to request their childs information is not used for this purpose by informing the clinical team at the unit they were treated in. This matches the method of opt out provided for the NNRD itself, however the applicants have confirmed that the opt out process will be specific for neoWONDER. The national data opt out will be applied, alongside separate additional opt outs applied by NNRD, CRIS and PICAnet.

The Committee commented that the planned display and dissemination of the patient notification was very good, and all outlets seemed appropriate.

The CAG however did require some changes to the content of this notification to ensure clarity. The CAG noted that it was quite a long document, and it would be preferable to develop a layered approach, of one short notification describing the linkages and how to opt out, which has a link to a longer more detailed notification document if people wish to read further information. This is in line with advice from the ICO on how best to present privacy information What methods can we use to provide privacy information? | ICO.

Members felt that the notification is not fully detailed, and contains some inaccuracies regarding flows and facts which will need to be amended (as described in the advice form). For example the *statement 'They (TTPs) will not be given any new data not already held'* is factually correct, and of course can be left in the notification, as advised by the parents group. However, the TTP's will be given confidential patient information, and it is important that this is communicated to participants, as the original statement alone implies that no data is flowing. The CAG identified other statements in the notification which they felt could also be misleading, such as '*no baby will ever be identified'.* It was noted that in some of the conditions studies, there may be relatively small numbers, and despite all safeguards and the removal of identifying information

it is a bold claim to make that may not hold true. Another example is the statement that '*taking part in the research is entirely voluntary*' as this implies the research is consent based, when in fact it is dissent based. The applicant is required to modify the notification materials to correct these inaccuracies.

Regarding the opt out approach, the Members agreed that the separate study specific opt out for neoWONDER needs to be made clear on the notification documents rather than referring to the NNRD opt out. It was commented that to ensure the opt out option was valid, the notifications should be displayed for at least 6 weeks before any data extraction, to allow participants time to opt out.

Members also commented on the 'whole unit' opt out option provided as part of conditions for using NNRD data. Noting that this is not within scope for CAG as part of this application, but it was felt that this may possibly mean that some people may want to be part of neoWONDER and are unable to if their unit has opted out. They would be interested in an update as to whether any units do decide to opt out of this linkage study. The applicant is asked to provide this at annual review.

Patient and Public Involvement and Engagement

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

The applicants have carried out an extensive patient and public engagement REC approved workstream (national survey, focus groups and interviews) which demonstrated support from over 500 parents and ex-patients for the use of routine data and linkage without consent. The applicant states that this was deemed acceptable as long as there is a notification strategy for opt-out processes and strong engagement workstreams. Within the survey undertaken, there was an explanation for the need to seek CAG support to link these data without explicit consent. The majority of people supported the use of confidential patient information without consent, and the negative responses were mostly based around requiring further information. A letter of support from BLISS has been provided, and one of the co-applicants is also a parent with experience.

The Committee commented that the applicant has clearly put in a lot of effort to communicate with patients and the public, and has made extensive changes to the application as a result. There is a lot of engagement with various stakeholders, and the CAG recognised the amount of work undertaken, and the efforts made to listen to the feedback and make changes as a result. It was commented that the only group that appeared to be missing from the patient and public involvement undertaken was teenagers who would potentially be part of the cohort. It is suggested that patient and

public involvement should be undertaken with teenagers. The applicant should use these ongoing discussions as an opportunity to improve patient notification materials, and to explore the reasons why some people would not be happy to share their data for the described purposes, as the members commented that there were more negative responses than might have been expected. It is noted that the applicant had plans to undertake further in depth interviews with this specific group of people.

Exit strategy

The exit strategy is pseudonymising the data for analysis, which will be effectively anonymous to the applicant. Support is only required until linkage is complete, estimated to be March 2023. The Committee were content with this exit strategy.

Multiple pseudonymous datasets

It was commented by the Committee that there did not appear to be a reason for the applicant to require a pseudonymous linked English health dataset to be retained at the NDAU, in addition to the linked NPD and health data that is retained in the ONS-SRS. The applicant is asked to provide justification as to why multiple datasets for analysis are required to be held in two different locations.

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. Please provide further justification for the inclusion of SLaM-CRIS data, within one month from the date of this letter.

2. Please provide an updated patient notification document for CAG review, within one month from the date of this letter. This should incorporate the following changes;
    a. Incorporate a layered approach
    b. Remove inaccuracies, and ensure clarity, using the feedback in the advice form and the letter
    c. Ensure neoWONDER specific opt out is clearly provided

3. The patient notification should be displayed for at least 6 weeks prior to data extraction.

4. Please provide an update as to whether any individual units have opted out of neoWONDER at annual review.

5. Please undertake ongoing patient and public involvement with teenagers, to explore the acceptability of the use of confidential patient information without consent, and provide feedback to CAG within six months from the date of this letter.

6. Please provide justification as to why multiple datasets for analysis are required to be held in two different locations, within one month from the date of this letter.

7. Favourable opinion from a Research Ethics Committee. **Confirmed 02 June 2021**

8. 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: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for these organisations have been assessed as 'standards met' by NHS Digital**

b. 21/CAG/0085 - The Child Health Clinical Outcome Review Programme (CH-CORP)

Context

Purpose of application

This Healthcare Quality Improvement Partnership (HQIP) commissioned non-research application from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) set out the purpose of undertaking a rolling programme of topics under the Child Health Clinical Outcome Review Programme (CH-CORP) core methodology, which aims to review the organisation of, and clinical care provided to children and young people up to their 25th birthday, by undertaking confidential reviews of case notes. Previous related applications for specific studies in this area include 15/CAG/0210 and 18/CAG/0127, however this application falls under a new contract with HQIP and it has been set up in a rolling manner so applicants apply a core methodology but start a new topic each year, as is undertaken as part of the Medical

and Surgical Clinical Outcome Review Programme (PIAG 4-08(b)/2003), where CAG have supported the core method and applicants submit an amendment with a new protocol for each new study started. The application activities are carried out across England, Wales, Northern Ireland, Guernsey, Jersey and the Isle of Man; however, the CAG remit extends only to data generated in England and Wales.

This application is for the Child Health Clinical Outcome Review Programme (CH-CORP) core methodology, to allow NCEPOD to run confidential enquiries to improve the quality of care for future young people. Although aiming to identify areas for improvement, NCEPOD will also highlight examples of good practise, and provide tools to help providers make changes and monitor the impact they are having. The recommendations made by NCEPOD over the last 30 years have had considerable impact on healthcare.

This application is additionally for their first proposed study; 'Transition from child to adult services study'. The purpose of this study is to explore the barriers and facilitators in the process of the transition of young people with complex chronic conditions from child to adult health services. There is evidence that for many young people with complex conditions and their families, this can be an apprehensive time as it is often associated with a dislocation of care and a deterioration in health and wellbeing.

Applicants plan to use standard NCEPOD retrospective questionnaire and case note review methodology on a sample of patients from various healthcare providers, who match the inclusion criteria for a specific study. Confidential patient information relating to all eligible patients will be reported to NCEPOD from participating healthcare providers via a patient identification spreadsheet. This data is entered onto the NCEPOD database, and a pseudonym applied unique NCEPOD number. From this, the data will be sampled for those to be included in the study. The patient identifiable data for those not included in the study are kept until all sampling is done, just in case re-sampling is required, and then removed from the database at the earliest possible opportunity as it is not needed.

The clinician(s) involved in the patient's care are then notified that they need to complete a questionnaire, and return copied extracts of the case notes, to undergo peer review. The NHS number and date of birth alongside the NCEPOD number is used to enable clinicians to identify the correct patients, and the questionnaire is returned back pseudonymously via the online questionnaire system, using only the NCEPOD number. Depending on the study, case notes will be requested from all relevant healthcare services. If a young person is identified and tracked across a number of care settings, case notes will be requested from all organisations. Case notes are returned in an identifiable format, and upon receipt at NCEPOD, patient identifiers are removed by the NCEPOD team as soon as possible after receipt but no later than two months, if not already done so. Care providers are encouraged where possible to remove patient identifiable data, however the applicants understand this does represent an additional burden to the direct care team.

A multidisciplinary group of clinical case reviewers will be recruited to assess the case notes and questionnaires and provide their opinion on what went well and what did not go well during the care under review. NCEPOD staff will ensure there is a mix of

specialties at each meeting from across the UK. Note that all patient identifiable data are removed from case notes before being seen by case reviewers. The set of case notes is only identified by the 'NCEPOD number' allocated to the case.

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.

For the **Child Health Clinical Outcome Review Programme (CH-CORP) overall;**

Cohort	In general, patients from birth up to their 25th birthday will be eligible for inclusion. However, the inclusion criteria will be specific for each topic and will be highlighted in the amendment form when each study protocol is submitted. Support is also in place for those who are deceased.
Data sources	Case notes from all organisations that provide care to patients aged 0-24 years, such as, but not limited to; secondary/tertiary care, community care. primary care, mental healthcare, independent healthcare or hospices
Identifiers initially collected for all patients	This could include but are not limited to the below; 1. NHS number 2. Hospital number 3. Date of birth 4. Sex

	5. Diagnosis and/or procedure code 6. Date of admission 7. Source of admission 8. Date of discharge/death 9. Additional healthcare organisations 10. Potentially partial postcode if an aspect of a study was very focused on deprivation
Identifiers required for linkage between organisations purposes (sampled patients)	This information will be used to notify the clinician who needs to complete a questionnaire, or the local contact at the healthcare provider who will send/scan copied case note extracts to NCEPOD. • NHS number • Hospital number • Date of birth • Sex • Date of admission – where applicable • Date of discharge – where applicable • NCEPOD number – for future pseudonymisation where possible • NCEPOD 'site identification – for future pseudonymisation where possible
Identifiers required for analysis purposes	For the clinical questionnaires and case reviewer data – no identifiers are needed as all data are linked by the NCEPOD number only. Note that NHS number is removed.
Additional information	**Case note review** For each sampled patient included in the case review, NCEPOD will obtain copied extracts of the relevant parts of the patient's notes to allow the peer review process to take place. Each protocol will specify what is needed and for what time period. NCEPOD have access to all the information within the returned case notes and also use the case notes to identify other providers of healthcare services for each patient, that might be relevant to the patient pathway, and to whom NCEPOD would want to send a clinical questionnaire or request additional notes. On receipt of the case notes all patient identifiable information will be removed and substituted with the NCEPOD number. All case notes are securely destroyed at the end of the study.

For **Transition from child to adult services study specifically;**

Cohort	All patients aged 13-24 years, with a complex chronic condition, transitioning from child to adult health services and provided care between 1st October 2019 - 31st March 2021 (approximately 123,564 patients) Patients will be randomly selected from a larger sample for questionnaires (4000 patients) and case note reviews (1000 patients). Note these figures account for response rates.
Data sources	Case notes from all organisations that provide care to patients aged 13-24 years with a complex chronic condition, including primary care, community care, and secondary/tertiary care Notes requested relating to Transition will include: • Clinic letters • Discharge summaries • Transition documentation (including 'Ready Steady Go' and Transition plans) • General multidisciplinary team notes • Education, Health and Care Plans (where available) • Moving on Passport/Transition passport • Care plans • Treatment escalation plans
Identifiers initially collected for all patients	1. NHS number 2. Hospital number 3. Date of birth 4. Sex 5. Diagnosis and/or procedure code
Identifiers required for linkage between organisations	• NHS number • Hospital number

purposes (sampled patients)	• Date of birth • sex • Date of admission – where applicable • Date of discharge – where applicable • NCEPOD number – for future pseudonymisation where possible • NCEPOD 'site identification – for future pseudonymisation where possible
Identifiers required for analysis purposes	For the clinical questionnaires and case reviewer data – no identifiers are needed as all data are linked by the NCEPOD number only

Confidentiality Advisory Group advice

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

Public interest

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

The Members were very supportive of this application, agreeing that there is no doubt about the medical purpose, and the clear public interest in this overarching approach. The CAG also agreed on the medical purpose and public interest for the specific 'Transition' application, noting that the transition period is fraught and difficult to negotiate.

Practicable alternatives

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

- Minimising flows of identifiable information

The Committee commented that the current methodology of disclosing confidential patient information appeared to be via encrypted spreadsheet, which was then sent from nhs.net email address to nhs.net email address. The CAG realised that this is a standard methodology but felt that it was subject to human error and feels out-dated.

Members queried if the applicant had considered revisiting how the data flows were undertaken, considering improvements in data security and technology over the years, as it may be possible for a more secure method to be used to transfer data. Safe and secure alternatives such as secure file transfer protocols (secure FTP) could be a good alternative, although noting that CAG do not prescribe these specifics, and the applicant is advised to discuss this level of detail with information governance experts.

Furthermore, the Committee recognise that this issue is potentially one that sits with HQIP as the commissioners, and therefore the applicant is not expected to change this methodology as part of this application. However, the Members would like some assurance that the methods of disclosing confidential patient information would be re-visited to explore if there were more secure alternatives available and the Members be provided with feedback at annual review.

- Feasibility of consent

The applicants provide a number of reasons to justify why consent is not feasible, including the large sample size of the initial case reported information, the potential for some patients to be deceased, the retrospective nature of the activity, and the potential for sample bias through operation of a consented process as this would need to be taken by treating clinicians. The CAG were content with these justifications and considered that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is required to identify a sample of eligible patients, and then to undertake linkage between different organisations who may have treated the same patient, and to ensure that clinician questionnaires and case notes can be linked. The applicants have considered pseudonymisation of notes at the healthcare sites; however, this would be a burden on those returning notes and may also lead to errors and failure in linkage to the questionnaires. Analysis is undertaken on pseudonymous data, that the reviewers are unable to re-identify. The only time that an individual case is isolated, is where a case review raises such a concern that current patients could be at risk. These cases are referred back to the Medical Director/ Responsible Officer of the healthcare provider concerned in order that appropriate action may be taken. This approach was given support by the GMC in 1998 and 1999 and was ratified by the NCEPOD Steering Group in March 2001, September 2003 and April 2006. More recently this process has been adopted by HQIP across all Clinical Outcome Review

Programmes. This meets the requirements laid down by the GMC in Good Medical Practice.

The Committee were content that the activity could not be undertaken in a less disclosive manner and using pseudonymised or anonymised information would not be 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.

For the **Child Health Clinical Outcome Review Programme (CH-CORP) core methodology;**

In general, local contacts are provided with a general poster about NCEPOD to be displayed in clinical areas – this is also available in Welsh. This is also displayed on the NCEPOD website. A general privacy notice is also displayed on their website.

Prior to data collection for individual studies, NCEPOD will contact all healthcare providers and provide a specific poster and patient information leaflet, for display in waiting areas or to be given to clinicians to provide to patients. Social media is used to advertise that the activity is taking place – Twitter and Facebook being the most commonly used. Links are added to the website (*www.ncepod.org.uk*) where the same poster and patient information can be found, as well as information on opting out. Patient groups and third sector organisations are asked to help share information about the study. These organisations will be listed on the study specific communications plan as they will vary depending on the topic under review.

All patient facing material will state how to opt out of the study, including poster and patient information leaflets, which will be displayed on NCEPOD website and in local clinical areas. The national data opt out will also apply.

The Members were content in general with the standardised notification and opt out approach. However, it was noted that the general NCEPOD poster for clinical areas and the website does not explain what NCEPOD is, and it was felt that this useful information should be included.

It was also noted that the communication approach should vary from sub-study to sub-study depending on the ages of the children and young people involved, and it is likely

in these cases that only one poster and information leaflet may not be appropriate for all age groups. It was also noted that as some of these children may be very young, there may also need to be notification materials created that are aimed specifically at parents or carers. The Committee considered that in these cases there may occasionally be times where a child may wish to opt out, but the parent wishes for their data to be retained, or vice versa, although noting that this would be a very rare occurrence. The CAG were therefore interested in the policy position of the applicant regarding conflicting opt outs.

For **Transition from child to adult services study specifically;**

Information regarding this activity will be made available via the NCEPOD website and sub-study specific posters are provided to participating hospitals/GPs to inform patients that data may be collected. A Patient information sheet is additionally provided for clinicians to provide to patients. A communication plan has also been provided, which contains a list of organisations to contact to help share information about the study. This would include providing organisations with some text they could put in a newsletter, attending online/physical meetings held to talk about the study and tagging them in social media posts on both Twitter and Facebook to help promote the work both with patients/parent carers and healthcare professionals.

The poster provides detail of how a patient can opt-out – this is by contacting NCEPOD directly via post, email or telephone. The patient information sheet also provides an opt out option, and additionally the national data opt out will apply.

As per the core methodology, the CAG were content with where the notification would be displayed, and the use of social media, and how the opt out option will work. They did however have some comments on the content of the notification, considering that a poster aimed at a 13 year old may greatly differ in content to one aimed at a 24 year old, however, the applicant had tried to use only one poster and information leaflet, which may have had the unintended effect of sacrificing clarity for simplicity. For example, the phrasing regarding data being put into a ‘big pot’ may be perfect for 13 year olds but may be oversimplifying for a 24 year old. The Committee are not prescribing that the applicant must split the patient notification for the transition study into 2 separate notifications, however they do request for a plain English review of the transition notification materials to ensure the language is clear and informative without being condescending or ambiguous. Members again noted that they would like a description of NCEPOD to be included on the transition poster, noting it is explained well in the leaflet.

The CAG also commented that the phrasing regarding 'we will see what works well and see what does not work well' sounds a little like research, and would like the revised transition notification materials to be clear that this activity is a non-research activity.

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.

For the **Child Health Clinical Outcome Review Programme (CH-CORP) core methodology;**

NCEPOD has a panel of eight 'permanent' lay representatives involved across work programmes who sign off protocols and review data before publication as well as participating in the study advisory groups.

The applicant ensures patient input for each individual sub-study by inviting patients to sit on the study advisory group as part of the design process. Patient focus groups/interviews are undertaken at the start of a study to get a wider feel for the themes that should be reviewed. Patient representative/third sector organisations help the applicant engage with patients (e.g. Local Reporters, and relevant charities), and anonymous online surveys are undertaken to get a wider view of patient experience.

The applicants have asked their users thoughts on using identifiable data without consent with regards to the core methodology. Initial responses are positive, and more responses may be returned. The CAG were content with the level of patient and public involvement undertaken, however they would like some feedback regarding any further comments returned, as the applicant has noted that more responses are expected. The applicant has also noted that for all future sub-studies, exploring the use of confidential patient information without consent will be built into patient and public involvement undertaken in order to build up comments of support and recognise any areas of concern that could be addressed.

The Committee also were interested in the turnover of the eight permanent lay representatives, querying at which point a lay person becomes an expert.

For **Transition from child to adult services study specifically;**

For the Transition study, focus groups were held with parent and carers of young people and there are patient representatives on the study advisory group. The findings from the focus groups were shared at the first study advisory group meeting, and the themes that participants felt were important have fed into the study objectives. All young people

and parents or carers involved have been made aware of the study method and no concerns have been raised about the use of patient data. However, as the question was not explicitly asked, the applicant has again (as a response to queries) asked the study advisory group and focus group participants thoughts on using identifiable data without consent with regards to the transition study. The one initial response is positive, and more responses may be returned. The CAG were content with the level of patient and public involvement undertaken, however again, they would like some feedback regarding any further comments returned, as the applicant has noted that more responses are expected.

Exit strategy

Each item of identifying information is deleted at the earliest opportunity during each specific study. Three months after publication all electronic data are anonymised, and all paper data are securely shredded. The patient identifiable data for those not included in the study are kept until all sampling is done, just in case re-sampling is required, and then removed from the database at the earliest possible opportunity as it is not needed.

NCEPOD was commissioned for a three-year contract starting on January 1st 2020, and with a possible extension for a further two years starting in 2023. Support is requested on an ongoing basis, in line with other applications of this type.

The members were content with this exit strategy.

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 specific and standard conditions of support as set out below.

Specific conditions of support

1. Support extends to data generated in England and Wales only.

2. Please re-visit the methods of disclosing confidential patient information to explore if there are more secure alternatives available and provide feedback at annual review.

3. Please update the general NCEPOD poster to explain what NCEPOD is and provide an updated version to CAG within one month from the date of this letter.

4. Please provide some more detail on whether different approaches will be considered for different sub-studies, specifically regarding age appropriate patient notification, how you will differentiate between parent/carer and children notifications, and a statement regarding the policy that will be followed regarding any conflicting opt-out requests (from a parent/carer and their child), within one month from the date of this letter.

5. Please revise the transition notification materials to ensure the poster explains what NCEPOD is, ensure there is no suggestion of research activity, and re-consider the language used to ensure they are written in plain English, and provide updated versions to CAG within one month from the date of this letter.

6. Please provide any detail regarding turnover of the eight permanent lay representatives, within one month from the date of this letter.

7. Please provide any further patient and public involvement feedback surrounding the use of confidential patient information without consent, that is noted as expected for both the core methodology and the transition sub-study, when it is available.

8. 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 **2019/20** DSPT review for **National Confidential Enquiry into Patient Outcome and Death (NCEPOD)** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 5 July 2021)

   Due to the number of participating care providers involved it is the responsibility of NCEPOD on behalf of HQIP, as controller, to ensure that all organisations disclosing confidential patient information to NCEPOD 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.

c. 21/CAG/0087 – Brain tumouR Information and Analysis Network (BRIAN) Databank

Context

Purpose of application

This application from The Brain Tumour Charity sets out the purpose of medical research that aims to create a linked research database, web application and mobile application called Brain tumouR Information and Analysis Network (BRIAN) Databank. The web app/mobile app allow patients, carers, researchers and The Charity to input data and extract anonymised information about brain tumours, although this element does not require CAG support. This research database will contain brain tumour data linked with health outcomes, and patient reported quality of life outcomes, and will be shared with researchers in pseudonymous format in order to identify better treatments for brain tumours. This is in line with the charity's strategic objectives which are to halve the harm caused by brain tumours and to double life expectancy. This research database application has been developed since 2017 by the charity to help remove barriers to brain tumour research, such as spending funds on data.

Brain tumours are the largest cause of cancer death in children and adults under 40. Over 88,000 people are currently living with a brain tumour in the UK. Whilst survival has doubled across all cancers, ten year survival rates for brain tumours have improved little for adults in over 40 years. Quality of life for many people who have had a brain tumour is severely impaired. Research in the form of clinical trials is a vital step in making sure that new treatments reach patients. Only 3% of brain tumour patients, compared to 7.5% of all cancer patients are currently enrolled in clinical trials, yet research shows that people want to be asked. This is an issue that the applicants aim to help address through BRIAN.

BRIAN already receives unlinked pseudonymous brain tumour data from Public Health England (PHE) and NHS digital, and the Secure Anonymised Information Linkage (SAIL) Databank, and already has about 4000 patient users inputting quality of life outcomes. This CAG application is for the receipt of identifiable data from national data sets alongside brain tumour data, for two purposes. Firstly, for the applicants plan to undertake linkage between the clinical datasets, and secondly, to enable the applicants to receive name, address, and other contact details, in order for the charity to contact people to invite them to input quality of life data, and to inform them of clinical trials that they might participate in. The app also includes search functionality to help patients identify clinical trials that are relevant to their own condition so that they can contact the team running the trial to discuss their eligibility. The Databank is expected to grow in time as the BRIAN project obtains more healthcare data from other sources, with the

applicant understanding that a CAG amendment is required for additional identifiable data sources.

The applicants aim to request identifiable National Cancer Registration and Analysis Service (NCRAS) data from PHE, identifiable outcome data from NHS Digital from Hospital Episode Statistics (HES), ONS civil registration data, Diagnostic imaging datasets (DID), identifiable data from Clinical Practice Research Datalink (CPRD), and identifiable Welsh data from various sources. The applicant states contact details will be sought from PHE but if this is not successful this will be requested from NHS Digital (Personal Demographics Service - PDS). Each identifiable dataset that The Charity receives will be split into two separate components on receipt; a pseudonymous BRIAN Health ID number will be applied, and confidential patient information (e.g. name, NHS Number, Hospital ID Number, GP registration, date of birth, date of death, address, postcode, phone number, email address) will be stored in an encrypted identifiable database in BRIAN, alongside the BRIAN health ID. The de-personalised healthcare data (e.g. diagnosis, treatment, appointments, medication, molecular, imaging and omics data and quality of life data) would be stored in a pseudonymous healthcare database, alongside the BRIAN health ID. A key between the BRIAN Health ID and identifying information is used to link the personally identifiable data to the healthcare data. Only pseudonymous data will be released to researchers.

The research database has a Data Access Board which will oversee each application and the Terms of Reference for this Board has been approved by the Patient Mandate Group. The Data Access Board will ensure each applicant meets the terms of the Data Sharing Agreement. For some researchers The Charity would only consider allowing access to the data within The Charity's Trusted Research Environment (for example, for researchers from countries outside of the UK), whereas for others, The Charity would be prepared to consider disseminating data for use by the researcher in their own digital environment. Each research project is allocated its own list of BRIAN IDs to ensure that there could be no cross-referencing between data applicants.

A recommendation for class 1, 2, 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	All children and adults diagnosed with a primary (benign or malignant) brain tumour in the UK, including those that have died since 2008 This is estimated to be 148,000 patients since 2008, with approximately 12,000 added at each annual refresh.
Data sources	7. **Public health England (PHE)** National Cancer Registration and Analysis Service (NCRAS) data; • NCRAS - Cancer registration dataset • NCRAS - Cancer Waiting Times (CWT) dataset • NCRAS - Radiotherapy Data Set (RTDS) • NCRAS - Systemic Anti-Cancer Therapy (SACT) dataset • NCRAS – NCRAS linked HES and DID data 8. **NHS Digital;** • Hospital episode statistics (HES) • Diagnostic imaging datasets (DID) • ONS Civil registration dataset 9. Clinical Practice Research Datalink (CPRD) - Primary Care Dataset 10. Patient Reported Outcome Measures (PROMs) from users of the app (support not required) For patients treated in Wales applicants propose to obtain the following datasets: 11. NHS Wales Informatics Service (NWIS): • Critical Care Dataset • Diagnostic and Therapy Services Waiting Times Dataset • Emergency Department Data Set • Outpatient Dataset

	• Outpatient Referral Dataset • Patient Episode Dataset for Wales (PEDW) • Postponed Admitted Procedures Dataset • Referral to Treatment Times Dataset 12. Office for National Statistics (ONS) - Annual District Death Dataset (for Wales) 13. Welsh Cancer Intelligence & Surveillance Unit (WCISU) dataset 14. Welsh General Practices - Welsh Primary Care GP Dataset 10. Welsh Results Reports Service (WRRS) - Pathology Dataset
Identifiers initially requested and retained in encrypted identifiable database (including for purposes of writing to participants)	1. Name, 2. NHS Number, 3. Hospital ID Number, 4. GP registration, 5. date of birth, 6. date of death, 7. address, 8. postcode, 9. phone number 10. email
Identifiers required for linkage purposes	1. NHS Number 2. Name 3. date of birth 4. Hospital ID number (if required) 5. GP registration (if required) 6. BRIAN health ID
Identifiers required for analysis purposes (retained	7. Ethnicity 8. Year of birth 9. Gender 10. Postcode is modified to LSOA, district, electoral ward

in pseudonymous research database)	11. Date of death (Retained in full format in the separate identifiable database. Date of death in month/year format only is retained in the pseudonymous database for analysis.) 12. Date of birth (Retained in full format in the separate identifiable database. Date of birth in month/year format only is retained in the pseudonymous database for analysis.) 13. BRIAN health ID
Additional information	The frequency of data collection will vary depending on the source. BRIAN users could be entering data daily, but The Charity expects data from national clinical datasets to be updated annually

Confidentiality Advisory Group advice

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

Public interest

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

The Members were agreed that this application has a clear medical purpose and was in the public interest. They felt it was important to try to remove barriers to research, and were in principle very supportive of the application.

Whilst this application has been deferred because of the reasons set out below, Members wish to encourage the applicants to take advice and resubmit this application. It is also noted that the applicant attempted to receive pre-application advice from the Confidentiality Advice Team (CAT), but this was not possible due to the email request not being received. If the applicant wishes to access pre-application advice prior to a future submission, they are advised to ring the CAT, providing all previous submission reference numbers, for example 21/CAG/0087 and 19/CAG/0128, to ensure this service can be provided.

Academic advice

The Committee considered the application was not yet in a supportable format. There was insufficient detail about how the proposals would be delivered and the application was confusing to read. Given the size, scope and ambition of the proposed database involving a very large breach of privacy, Members felt it was essential that the database was designed to ensure its configuration was optimal from the outset. The applicant is advised to reach out to academic research experts and information governance specialists for advice in order to strengthen the application and to ensure the research database is as suitable as possible for purpose. Examples of specific research questions should be provided in a resubmitted application.

Scope

The Members had a variety of concerns regarding scope of support. These should be clarified for a future application.

Members felt that although they understood in a broad sense the scope of support the applicant was requesting (receive identifiable information from third parties, link it together, and use it to contact patients), they were not clear on the specifics required. CAG support is provided for specific data flows, between specified organisations and for specific purposes. The data flow diagram provided gave a general overview, but did not label the specific organisations and data items. This lack of detail was reflected elsewhere in the application and other supporting documents.

It is not clear from where the applicant is receiving confidential patient information regarding Welsh patients. The supporting email from Digital Health & Care Wales (DHCW) (formerly known as NHS Wales Informatics Service, NWIS) was confusing, as the applicant described seeking pseudonymous information (rather than identifiable information), and within the 'pseudonymous' flow, had mentioned date of death which is a direct identifier and would require a legal basis under common law to receive. For a future application, each Welsh data source and data flow needs to be clearly defined.

The applicant has confirmed as a response to queries that the database would be requesting identifiable data from CPRD, however it was the understanding of the Committee that the CPRD would not be able to provide identifiable data. In a future application, this also needs to be clarified, including supportive communications from CPRD that the proposal is possible.

It is not clear where contact details are being sourced from. The applicant has stated that they may be received from PHE, or *'in the event that they prove unable to provide this information, then we [the applicants] would approach the PDS'.* It is unclear why

this is not yet clarified, as it is an important element of the application. This needs to be clarified and confirmed by the third party providing the contact details for a future application.

Supportive communications should be provided from PHE, NHS Digital, CPRD, and any other third party providing these datasets, to ensure that the flow of data is possible, and to be clear where 's251' support is required. The applicant has stated that all communications with these third parties have not been in written format, however this would be essential for a future application.

The letter which is being proposed to be sent out has not yet been developed, and was therefore not available to review. It is therefore not entirely clear what support under the Regulations is requested, as the members have been unable to review what patients would be contacted about. The content of this letter is of key importance, as this would be an unexpected letter coming from an organisation who is processing their confidential patient information without consent. Further details are presented below in the section on notification. The scope of support required regarding this particular contact needs to be clearly defined in a future application, as CAG support is provided for specific purposes.

Practicable alternatives

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

- Minimising flows of identifiable information

Members felt that a query needed to be answered surrounding why a Trusted third party such as NHS Digital or PHE could not undertake the extensive linkages proposed. It was noted that the applicant would likely need some identifiers in order to link the clinical data to any later patient inputted quality of life data, however this could be undertaken with fewer identifiers than currently received.

- Feasibility of consent

Applicants cite large numbers (88,000 people currently living with a brain tumour in the UK) as the primary rationale for not seeking consent, as it is not practicable to consent

each individual. However, they do propose to write later to all relevant individuals to invite them to participate in the Charites database and clinical trials. They also cite the importance of inclusion of those that have died or lack capacity, to ensure a representative database.

They also state that it would not be possible seek consent as '*we would need to be able to specify upfront in the consent forms and patient information sheets details of the full range of research projects that researchers would want to use the data for. In practice it would be impossible to identify all such projects upfront.'* However, this is not generally the case for research databases – it is possible to design a consent process that provides either generic approval for future research or permits contact for specific future research projects. If it is possible to consent patients regarding the receipt of identifiable data and linking this information together, then that would constitute the exit strategy from support, as CAG support cannot be provided if there is a practicable alternative. The CAG were not convinced that consent was not a practicable alternative to perform the linkages. Though they accepted the justification provided surrounding the deceased, they did feel that consent for information flows and linkage could be possible from those people who are already inputting data into the app, or those who agree to input data into the app as a response to the invitation letter. The applicant should explore this possibility for a resubmission. The Members also noted that it should not be difficult to describe the particular types of research that may be undertaken using data from the research database, and that it should be possible to design an appropriate consent form to be part of the research database.

The members also noted that between January 2018 and September 2019 the applicants did actively seek informed consent from patients, securing 650 consents in that time, which represents less than 1% of the UK's people with brain tumours. However, it is not clear what the applicants were seeking consent for at that time, or how eligible patients were identified. It seems that they may have been seeking consent to generally 'join the BRIAN database', rather than describing the process proposed in this CAG application. The detail of this 'consent' is important because CAG support cannot be provided for those patients who declined, or who did not respond. (managing-non-response-guidance-v1-2_Aplc9nj.pdf). The applicant is therefore asked to clearly describe what the previous requests for consent covered, provide the consent form used, and explain why this attempt was not successful. If the previous request for consent did cover the use of confidential patient without consent for the purposes described in this application, please explain how you will ensure people that declined or did not respond will not be included in all data received from all third parties.

In the application, it is stated that *'As of March 2021, we had removed 60 data subjects from the database in response to requests that we had received.'* However, it was understood that the applicant currently didn't hold any confidential patient information

without consent, so it is not clear how these 60 people were removed from their records. The applicant is requested to address this in a future application.

- Use of anonymised/pseudonymised data

Identifiable data for the population of brain tumour patients is required so applicants can link datasets from different sources. It is also required in order to contact patients about trials they are eligible for. The Members agreed it was not possible to undertake these elements without the use of identifiers.

Justification of identifiers

More detail is available in the section on 'Exit strategy' however members did not feel that the applicant had justified the retention of all identifying information for 25 years, instead of deleting or modifying any items.

'Patient Notification' and mechanism for managing dissent

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

A layered notification has been provided for review by the applicant, consisting of a patient notification entitled 'BRIAN and your data' which provides a link to a general privacy notice; The Charity's privacy policy. This notification is on the Brain Tumour Charity website. Patients will be encouraged to register for BRIAN and will do this through their website, distribution of e-newsletter; other periodicals and presence at conferences such as BNOS (British Neuro-Oncology Society). the charity has clinical champions throughout the UK promoting the benefits of BRIAN and a healthcare engagement team, helping to recruit people to BRIAN. Awareness will also be raised by healthcare professionals signposting patients to the site. One large NHS Trust is recommending to any new brain tumour patients that they sign up to BRIAN. Opt out of

this database is offered, and NHS digital would apply the national data opt out, additionally to PHE applying the cancer registry opt out.

The CAG did not consider the patient notification document to be appropriate in its current format. The CAG had a number of concerns about patient notification, both in terms of prior to the breach of confidentiality occurring and at the point of invitation. CAG comments and advice are subdivided below into three sections.

a. Notification - prior to the breach in confidentiality taking place

Members noted the research database requires a disclosure of contact details before any patients can be contacted to be asked for their consent to 'join BRIAN' or to consent for linkage to be undertaken. Therefore, members agreed it is imperative that efforts are made to inform the population about the trial before the breach has occurred, thereby reducing the risk of patients being surprised by the invitation to participate.

Adequate and appropriate notification of the cohort is a typical element for all CAG applications given 'section 251 support'. Placing notices on websites and using social media could provide notification of the breach that is intended to occur, and provide an opportunity for people to opt out of having their contact details disclosed and to avoid them receiving a letter they may not want. In this case, the notification must be displayed for an appropriate length of time before the disclosure, in order to allow time for people to opt out if they wish. As part of previous precedents CAG has experienced regarding other applications aiming to contact large numbers of individuals, the CAG had advised different ways to ensure sufficient coverage to notify the target population. Among these were use of local radio and television, various social media outlets, and local and national press. The Members did not discuss the level of coverage expected for this application for this specific breach, as the applicant had currently not provided any detail of this element. For a future application, the applicant is advised to consider how to notify their cohort regarding the applicant receiving their contact details, before this breach occurs, in order to provide an opt out mechanism.

b. Invitation Letter

The invitation letter will be the first point for many recipients where they become aware that their data has been used to invite them to be part of BRIAN research database. As such, it is imperative that the letter is clear about what has happened to date, to ensure clarity and maintain the public trust. The text of this letter is of importance, as the sending of these letters constitutes a breach in the common law duty of confidentiality, and will come as a surprise to these patients. No letter has been provided for review, as the applicant has not yet drafted this document. The CAG expressed concerns that the application did not appear to fully address the principle of 'no surprises' as

established by the National Data Guardian. Members were clear that this concept must be respected to maintain the public interest and confidence and trust.

The Members commented that for a future application this letter must be provided for review. This letter must detail to recipients how their data has been used, and by whom, in order to be invited, as well as the role of CAG. This should be included in the letter to provide clarity to recipients and be consistent across all communication channels. Within this letter, which the members understand is proposed to invite the participant to join BRIAN by inputting data, rather than consent into the research database, the disclosure of confidential patient information from third parties for the purposes of linkage needs to be explained, and an opt out of the data linkage element needs to be offered, including phone number, email and postal address. There should be a separate invitation letter designed for children and adults, if the applicant is planning on writing to children, which the CAG assumed they were considering the cohort has been described as '*everyone in England and Wales with a primary brain tumour'.* In addition, the Members wondered how the applicant will ensure they do not send letters out to people who may be deceased as it is not clear if applicants have considered this.

The Committee were unsure who the applicants were proposing to contact regarding clinical trials, and whether or not this was going to be only for people who are already signed up to the BRIAN app. This should be clarified in a future application.

c. Participant Notification

There is currently a notification and privacy notice available on The Charity website. However, these do not describe the initial breach in confidentiality regarding receiving contact details and only the linkages are described. The Members considered that the notification would need to be altered to ensure this detail of the initial breach was also described, in order to allow people to opt out if they wished to do so, and in advance of the breach having taken place.

Even taking the notification provided as the description of only the linkages, the CAG members were not content with the information provided. They commented that the notification did not provide a description of BRIAN, or for what purposes people's confidential patient information is used. There was no detailed information about the identifiers used for linkage from each dataset, and only PHE and NHS Digital were listed as sources and CPRD and the Welsh data flows were not described. Further, the descriptions of CAG are not correct; it is not a decision-making group and instead provides recommendations to the decision maker, the Health Research Authority in this case. This statement should be amended to include correct reference to the decision-making element. For example, *'The Health Research Authority has supported the activity, on advice from the Confidentiality Advisory Group, an advisory body which*

provides independent expert advice on the use of confidential patient information without consent in England and Wales, [etc].' Members were uncomfortable with the applicant stating the data is '*fully identifiable'* and that this is allowed by CAG, and felt this undermines the purpose of the Committee, as every effort should be made to reduce disclosures and pseudonymise information wherever possible. The sentence does not reflect the purpose of 's251' support, which is to temporarily lift the common law duty of confidentiality for as short a time as possible in the least disclosive way possible.

An opt out option was provided, but its extent was not clear. The comment '*Some parts of your old data, which will now be considered anonymous, will remain in BRIAN'* was queried, as all data should be removed if a person so requests. By implication there it appeared that of data would being used without consent even if participants did choose to opt out. The Committee were not clear if the applicant understood that opt outs are required to be offered for elements requiring 's251' support, and the legal basis provided by Regulation 5 cannot override dissent. The opt out option link did not provide contact details of who to contact in order to opt out, such as name, phone number, email and postal address.

Again, as the applicant has indicated they wish to include children, notification materials specifically for children of different age groups should be developed and included in any re-submission.

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 Charity conducted a survey in 2017 to seek views from brain tumour patients about sharing their healthcare data. This found that almost all of those diagnosed with a brain tumour would be willing to share information about their diagnosis and subsequent treatment in order to help develop better treatments. Of 270 respondents to the survey, 97% (262 respondents) agreed with the statement: "I would be willing to give my medical and health data to the data bank to help improve brain tumour treatment and care."

The Charity also established a Patient Mandate Group (BRIAN Champions) to provide guidance on the project and this group includes a cross section of people living with or caring for brain tumour patients, as well as people who have lost a loved one to a brain tumour. This group meets several times a year. The Charity tested the acceptability of processing and linking identifiable patient data without consent in June 2019 with the

Patient Mandate Group (15 members) and the group was unanimous in its support of the approach. At the Patient Mandate Group meetings that were held in November 2019 and May 2020 the Group (now 30 members) continued to fully endorse this approach.

The applicants also periodically sought views on the project from The Charity's Young Ambassadors programme (young adults aged 18-25 who are affected by brain tumours) who were supportive of using identifiable data without consent.

Around 50 patients, carers, clinicians, researchers and other specialists were individually interviewed, though this did not include discussions on using identifiable data without consent.

The CAG considered that the patient and public involvement undertaken had mostly happened some years ago, and it was unclear if these discussions were relevant to the current CAG application. The breaches in confidentiality for this application include receiving large amounts of identifiable data including name and contact details from several different sources, and linking them together to create a research database, and importantly to also contact every patient by letter. The patient and public involvement and engagement work undertaken in 2017 supported only the use of medical and health data - use of any identifiable data was not queried. It is unclear if the respondents would have supported the current design of the application. For a re-submission, the applicant is advised to undertake more up to date patient and public involvement, present the study design as proposed to CAG to the participants, and explore their views on the various proposed uses of confidential patient information without consent. Evidence will need to be provided to CAG, such as a copy of the presentation used, and any comments from participants.

Exit strategy

Data collected through the BRIAN app will be kept for 25 years or until data sharing agreements end / data subjects ask to be removed. As part of the response to queries, the applicant agreed for support to extend 5 years in first instance at which point a review into the continued need for CAG support will be undertaken. There appears to be no exit strategy for removal or modification of any identifying information.

The CAG did not feel that there was any justification for the retention of name, address, phone, number, email address, and other contact details without consent, for 25 years. The applicant should consider an exit strategy from 's251' support as part of a future application, to include modifying or removing identifiable information from the database at the earliest opportunity. It was noted by Members that this element of the research database appeared to be mailing list data, and it was felt that it is not appropriate to use

‘s251’ support to establish a mailing list to be retained, effectively indefinitely, without consent.

Data access Committee

It was noted that there is currently no lay representation on the data access committee. The applicant did suggest that this might be rectified in the response to queries. This should be ensured for a future application.

Research Ethics Committee (REC) Favourable Opinion

It is a condition of the Control of Patient Information (COPI) Regulations, under which the CAG operate, that a Favourable REC Opinion is in place for the proposed activity. The original Favourable Opinion for this application was given 16 August 2018, however this was regarding pseudonymous data only, that the applicant is not able to re-identify. On querying if the applicant had received a Favourable Opinion specifically regarding the activities describe in the CAG application, the applicant provided a REC Favourable Opinion given on 19 February 2021. On noting that the version of the protocol provided as part of the CAG application was dated June 2021, and therefore an earlier version would have been provided in relation to a REC amendment from February. The CAT corresponded with the REC in order to confirm what activities the REC amendment related to. The REC chair has confirmed that initially a provisional opinion was provided, and the applicant responded to queries, two of which are below;

- **The Sub-Committee also requested confirmation that consent will always be sought for future access to identifiable medical records.**

  For future data access requests that we make for identifiable data, we will either seek consent or seek to obtain CAG support under the Regulations to provide a legal basis in relation to the common law duty of confidentiality.

- **Please also state whether separate REC approval will be sought for processes in the case of deceased persons.**
  In the event that we were seeking to obtain identifiable data for deceased people, I can confirm that we would either seek separate REC approval or submit a further amendment to the existing REC approval.

Upon receiving the assurances above a Favourable Opinion was then issued. The applicant is currently seeking CAG support to receive multiple identifiable datasets, without consent, and to link them together, and the REC chair confirmed that it is clear from the response above that a further amendment to the REC is required regarding this element of the study, as the applicant refers to the future, rather than the February amendment. The applicant is also seeking identifiable information about deceased people as part of the CAG support, and the REC chair confirmed that a further amendment to the REC is also required regarding this element of the study, as the applicant refers to the future, rather than the February amendment. There is also nothing in the current REC favourable opinion to support the proposed contacting of patients by letter.

Therefore the CAG are unable to recommend support under ‘s251’ until the REC Favourable Opinion is in place for this proposed activity. However this is not the reason for the study deferral, and CAG would reconsider the application prior to Favourable Opinion being issued from the REC, and would be able to review alongside.

Additionally, the applicant has indicated that the REC opinion currently provided would allow them to release pseudonymised data to external researchers without that researcher having a separate ethical opinion from a REC, if the research purpose aligned to the research purposes of the database. However it is not clear what the specific research purposes of the database are, and how this would be applied. As part of a resubmission to CAG, the applicant is advised to seek REC advice on this point, in the context of the pseudonymised data having been extracted from a database containing identifiable information collected under ‘s251’ support, as this data collection is not currently supported by the REC favourable opinion.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Health Research Authority recommended that the application was deferred.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Please take advice from academic research experts and information governance specialists in order to strengthen the application.

2. Please provide examples of specific research questions as part of a future application.

3. As part of a re-submission, the application needs to provide absolute clarity on the data flows and data sources requested. The data flow diagram needs to clearly present which organisations are processing confidential patient information without consent, as CAG support is provided for specific data flows between specific organisations.

4. Supportive communications from third party providers of identifiable data are required for a future application.

5. For a future application, the scope of support regarding the contacting of patients by letter is required to be clearly defined, as CAG support is provided for specific purposes.

6. Please provide further justification as to why the linkages cannot be undertaken by a trusted third party.

7. Please explore if it is possible to take consent for the breaches requested as part of ‘s251’ support from at least the patients who are inputting data into the app.

8. Please describe what the previous attempted consent covered, in detail, explain why it was unsuccessful, and confirm that individuals who refused or did not respond will not be included in the proposed application. Please also explain how these patients were identified.

9. Please explain how 60 subjects were removed from the BRIAN database, when the database does not currently contain any confidential patient information.

10. Please consider how to notify patients regarding contact details for the purposes of sending a letter, which provides an opt out option of this breach, before the disclosure occurs.

11. The invitation letter must be provided for review. Please use the advice in the paragraph on notification materials, to ensure that the letter details how and why they are being contacted, it should describe the linkage process, and provide an opt out. There should be separate invitation letters designed for children and adults. The applicant should describe if any deceased checks are undertaken before sending these letters. The letters should make clear what the purpose of invitation is.

12. The linkage element needs to be more clearly described in the notification document. Please use the advice in the paragraph on notification materials, to ensure that all information is included, BRIAN is described, and the purposes of data collection and linkage is described, the function of CAG is clearly described, an opt out mechanism is offered with appropriate contact details, and age appropriate notification leaflets are developed for children.

13. Please undertake more up to date patient and public involvement, present the study design as proposed to CAG to the participants, and explore their views on the various proposed uses of confidential patient information without consent. For a re-submission, evidence will need to be provided to CAG, such as a copy of the presentation used, and any comments from participants.

14. Please consider an exit strategy from CAG support as part of a re-submission, and consider removing or modifying certain items of confidential patient information from the database, or provide clear justification as to why all data items are required to be retained.

15. Lay representation should be on the data access committee.

16. Please provide a Favourable Opinion from the REC regarding the proposed linkages using identifiable information without consent, and specifically the proposed use of a deceased persons data, by submitting a further amendment to the REC clearly describing the planned activities. A Favourable REC Opinion would also be required regarding the proposed contacting of patients by letter.

17. Please seek REC advice regarding the release of data to external researchers, and whether or not those researchers would require a separate REC review.

d. 21/CAG/0088 - Barts Structural Interventional Registry (BSIR)

Context

Purpose of application

This application, from Barts Health NHS Trust, aims to undertake medical research to understand the characteristics and outcomes in patients with valvular heart disease (VHD).

VHD is defined as any alteration to the normal structure and/or function of the heart valves and is often caused by a combination of cardiac and often non-cardiac factors. It is often caused by a number of diseases rather than a single one and often several valve diseases coexist in the same patient. Much research has been undertaken within strict conditions, but the real-world efficacy is not known for some sub-populations. The database will be used to test several hypothesis including but not limited to investigating characteristics of patients treated, complications of interventional and medical treatment, outcomes of patients and highlight structural and fluid-dynamics performance. This research will add substantially to the literature by providing real-world data from a leading valvular interventional centre.

Barts will send NHS Digital identifiers of the eligible cohort to extract data from HES and mortality data. This data, including date of death, will be returned to Barts and linked back to clinical information. Data that is subsequently required for research purposes under the terms of this support will be extracted by the clinical team, pseudonymised and provided to the research team for research purposes. Pseudonymisation will be achieved by assigning each patient with a study ID. A file will be created linking the study ID to the identifiable data. This file will be held by the CI on a Barts Health NHS server under password protection. Any data that is used for research purposes will only contain the study ID. This data will not have patient name, date of birth, postcode or NHS number. The application also explains how a data access committee will approve all uses of data required from NHS Digital, however after clarification from the REC, this application is for a specific study only, rather than a research database, and as such, any further uses of this data will require a further application.

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

Confidential patient information requested

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

Cohort	Any patient >16 years old with VHD referred to Barts Health NHS Trust from 01/01/2015 until present (Retrospective patients only included)
Data sources	15. Barts Health NHS Trust clinical data; (PACS, CRS, patient notes) 16. NHS digital; a. The office for national statistics (ONS) Mortality dataset b. Health episodes statistics (HES)
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Postcode 4. NHS number 5. Study ID
Identifiers required for analysis purposes	1. Study ID 2. Age 3. Date of admission 4. Date of intervention 5. Date of discharge 6. Date of death 7. Gender
Additional information	Annual extracts will be undertaken, but only for the retrospective patients.

Confidentiality Advisory Group advice

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

Public interest

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

The Members were agreed this application had a medical purpose, However they were less clear on the public interest in this activity; it was noted that this local dataset appeared to be collecting the same information as is collected by National Institute for Cardiovascular Outcomes Research (NICOR). Members queried if this is duplicating work, and therefore if the breach is necessary and in the public interest.

Scope

On reading the application there are many references to building a research database. As a response to queries, the fact the CAG form has been submitted as a study specific form, and after communication with the REC, it has been confirmed that this application in its current format is only for a study specific activity. ‘s251’ support is provided for specific purposes, and the members requested clarity on the specific research question that the applicant is proposing to answer. The applicant is requested to submit a further application should they wish to create a research database.

Practicable alternatives

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

- Feasibility of consent

The applicant reasons that as a retrospective dataset, seeking consent from every patient could affect the overall integrity of the data and lead to bias. In addition, due to the prognosis in this population, contacting relatives of the deceased could lead to anxiety and will not be possible. Not obtaining written consent was supported by the Barts Heart Centre patient public involvement survey. The large number of patients in this study will also make it very difficult to obtain informed consent for all involved.

The CAG agreed with the justifications provided for the deceased participants' data, noting that it is not lawful to ask for consent from a relative to use a deceased persons data in any case. However the Committee commented that as consent for this linkage was originally proposed in the protocol, but abandoned due to feedback from a patients and public involvement event, this undermines the arguments provided about it not being practicable to seek consent. As the purpose of 's251' is to provide a legal basis to undertake processing of confidential patient information outside the direct care team, if consent is not a practicable alternative, the applicant is requested to provide further justification for consent not being practicable, in the context of originally proposing it would be feasible.

- Use of anonymised/pseudonymised data

Confidential patient information is required for linkage of data with NHS Digital. Members commented that the identifiers proposed for linkage with NHS Digital datasets appeared standard, and agreed that linkage could not be undertaken without the use of confidential patient information.

Justification of identifiers

The applicant is currently proposing to receive the full date of death from NHS Digital, and use this for analysis. The CAG were supportive of the receipt of this data item, however they did wonder if this could be modified to something less identifiable for analysis, such as month and year of birth, or time from admission to death, before deleting full date of death, and thereby removing the need for ongoing 's251 support'.

Data sources

It was noted by Members that the CAG application only specifies linkage will be undertaken with HES and ONS mortality datasets at NHS Digital, however there are

also references to quality of life data and medication data. It was not clear what the sources of these data were.

‘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.

No patient notification materials have been provided. Whilst the national data opt out will apply there is no evidence of a local opt out, with the applicants stating they would not use a patients data *‘if they find out’* patients want to opt out, but not providing a mechanism for local opt out.

The CAG considered a patient notification document for this specific activity was essential. This document should explain the linkages with NHS Digital, and the data items required to undertake the linkage. The purpose should be described. A local opt out mechanism should be developed in addition to applying the national data opt out, and details of how to opt out should be clearly indicated on the patient notification. Opt out should be available via phone, email and postal address. The applicant should consider where to place this notification so that the relevant population may see it, and this is usually in clinical areas and on websites.

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 design of this study has been established through discussions within the clinical and research teams and has taken input of patients both informally and formally through the Barts Patient Public Involvement Survey carried out in November 2018, where 8 patients attended. Acquisition of data without prior patient consent, taken from NHS Digital, was specifically queried. The overall response from the 8 patients was that if the data obtained was going to be used for research purposes and ‘do good’ then they had no issue with the data being obtained. One patient made a comment on data

security and said ‘As long as the data is properly used and kept safe, I have no problem with it.’

The CAG commented that the patient and public involvement undertaken was from several years ago, and seemed to mostly be centered around quality of life. The Committee commented that more up to data and study specific patient and public involvement was required.

Exit strategy

Support has been requested for 5 years up to 1/10/2026, Which appears to be when the last linkage is undertaken. However, as the applicant has indicated that support is requested for a retrospective cohort only, it is not clear why it would take until 2026 to undertake a retrospective linkage. Support is required for the retention of any confidential patient information collected under ‘s251’ support, meaning support is required until full date of death is deleted. Therefore the exit strategy is not clearly defined at this time, please see section on ‘justification of identifiers’.

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 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, within one month.

Request for further information

1. Please confirm that this activity cannot be undertaken by using any datasets held by NICOR, and therefore justify the public interest in this activity.

2. Please confirm the specific research question or questions which this activity is proposing to answer.

3. Please provide further justification for consent not being practicable, in the context of originally proposing it would be feasible.

4. Please consider if full date of death can be modified for analysis, and deleted, to remove the need for continued support under Regulation 5.

5. Please confirm where ‘quality of life data’ and ‘medication data’ is proposed to be collected from, to evidence that the data required to undertake the study is actually available to use in order to answer the proposed research question.

6. Please confirm if the cohort is for retrospective patients only, from 1 January 2015, until the date support is provided.

7. Study specific patient notification should be developed and provided to the CAG.

8. A study specific opt out option should be developed.

9. Please undertake study specific patient and public involvement surrounding the specific activity requested in this application, focussing on the use of confidential patient information without consent.

Once received, the information will be reviewed at the next available CAG meeting in the first instance, and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information. If the response is satisfactory, a final support outcome will be issued.

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.

9. Favourable opinion from a Research Ethics Committee. **Confirmed 17 June 2021**

10. 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 **19/20** DSPT review for **Barts Health NHS Trust** and **NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 12 July 2021).

4. Any other business

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

Signed – Chair	Date
Minutes signed off via correspondence by Dr Tony Calland, MBE, CAG Chair	21/10/2021
Signed – Confidentiality Advice Team Katy Cassidy	Date 21/10/2021