Minutes of the meeting of the Confidentiality Advisory Group

20 May 2021 at Meeting via Teleconference

Present:

Members present:

Name	
Dr Martin Andrew	CAG member
Dr William Bernal	CAG alternative vice-chair
Ms Sophie Brannan	CAG member
Mr David Evans	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Ms Diana Robbins	CAG member
Mr Umar Sabat	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Alessandra Formica	Observer

1. Introduction, apologies and declarations of interest

The Chair welcomed Members to the meeting.

Mr Marc Taylor and Mr Myer Glickman gave apologies, and no conflicts of interest were declared.

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **15 April 2021** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **15 April 2021** meeting applications.

3. Annual Reviews

a. 17/CAG/0023 – National Bariatric Surgery Register

Annual review outcome

As a whole, it was noted that the activity was proceeding as planned and the justification for continuing support had been satisfactorily made.

However, as the annual review indicated that a condition of support applied at the last annual review had not yet been achieved, consideration of the annual review was carried out by the CAG.

Condition of support change

This application was supported in 2017, with a condition to report back at annual review regarding patient and public involvement undertaken. The first annual review was submitted in 2020 and the Chair felt the applicant had not responded appropriately to the original condition. Therefore after reviewing the 2020 annual review, three new conditions were applied:

1. The Group would like assurance that the NBSR have appropriate systems in place to ensure the next annual review is submitted by 6 April 2021 and conditions are adhered to.

2. The 2021 Annual review should be considered at a full CAG meeting.

3. The applicant is obliged to undertake patient and public involvement (PPI) surrounding the use of confidential patient data without specific consent, for the purposes required in the NBSR, and provide feedback within 6 months from the date of this letter.

The annual review submitted for CAG review sought to address these three conditions, and the group felt assured that the applicant now had appropriate systems in place regarding timely submissions of annual reviews, and the annual review was reviewed at the 20 May full CAG meeting. Therefore conditions 1 and 2 are met, and the main discussion was around condition 3.

In response to the condition surrounding undertaking patient and public involvement, a survey was designed to assess public and patient opinion on the collection of confidential data in the NBSR. A copy of the covering letter and a summary of the Survey are included for CAG review. The applicant also states that they have a patient and public involvement representative, who remains an active member of the NBSR committee.

The survey was sent to 16 patients, of which 10 replied. The people asked did seem to be content with some items of confidential patient being retained without specific consent for retrospective patients. However the retrospective collection of NHS number for patients prior to 2017 had the lowest support. The applicants noted that although the original CAG outcome provides them support to go back and add NHS number into the registry for the retrospective patients, this has not yet been undertaken due to logistical difficulties. The applicants wish to continue

with the same support as originally provided, to enable them to collect NHS number if they can at some stage.

Members noted that although some patient and public involvement has been undertaken, it is in a small cohort, and directed, using technical language (although noting these patients may understand this language). Despite the difficulties of having face to face meetings, members commented that it is possible to undertake patient and public involvement meetings in formats other than just a survey, for example using online platforms to encourage an involved discussion to get more value out of the patient and public involvement opinions, which can be very valuable. The CAG advised the applicant to try linking with charities to find a group of interested people. Therefore, a further condition is being applied for the applicants to undertake further patient and public involvement discussions. Over the next six months, a plan should be put into place regarding linking with charities and undertaking online patient and public involvement meetings. The plan should include a variety of ways of engaging with people. The materials used should use plainer language. Of note, the Members could not understand why there was support for other items of confidential patient information being retained, but not for the retrospective collection of the NHS number. This should be explored as part of further patient and public involvement, and it was noted that the response could be due to the explanation of the NBSR not being clear enough.

Members were happy to provide ongoing support, as the applicant had undertaken patient and public involvement as requested, but they did feel the NBSR would benefit from further patient and public involvement, and therefore are applying a further condition.

The NBSR is operating a consented model and only require CAG support for retrospective patients included in the registry. In the annual review, the applicant states *'There has been no request for data anonymisation in the last year'.* The members wanted some clarification regarding terminology, and hoped consent was being sought as intended. It was not clear whether an 'anonymisation' request is a withdrawal of the consent already provided, or a refusal of consent? Members were interested in the proportion of patients who were being consented prospectively as intended, as CAG support is not in place for the processing of any confidential patient information without consent after 2017.

Despite the NHS number for retrospective patients not yet being collected as support was originally provided for, other items of identifiable information are also retained for retrospective patients, so support is required for the registry. However, members did request an update as to the support provided regarding NHS number collected. The applicant has requested ongoing support for this, as it remains useful to collect NHS number in order to undertake any future linkages

that may be required. However, they have not provided a potential timescale for this, and Members requested clarification.

Security assurance

It is a policy requirement of the Department of Health and Social Care in England that relevant entities processing confidential patient information under support maintain a satisfactory security assurance level for the duration of support, with similar arrangements in Wales. The need to maintain appropriate security assurance is a condition of support for all applications.

The current status of relevant entities processing information under support is as follows:

1. The NHS Digital **2019/20** DSPT review for **Dendrite Clinical Systems Ltd** was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 25 May 2021)

Specific conditions of support (updated)

The following sets out the updated specific conditions of support applied against this application reference.

1. Please feed back to the CAG on further patient and public involvement undertaken and provide an ongoing plan within 6 months. This should include communications with charities, online meetings, and other ways of engaging with patients, using plainer language, and should explore the interesting response regarding NHS number.
2. Please confirm if an 'anonymisation request' is a withdrawal of consent or a refusal of consent, and confirm consent is being sought as intended, within one month from the date of this letter.
3. Please consider a timescale for the support provided regarding retrospective of collection of NHS number, and provide an update as to when this may take place, within one month from the date of this letter.

4. Revised Applications

a. 21/CAG/0071 – Congenital Hypothyroidism with Gland in Situ: establishing risk factors and outcomes using population-based data linkage methods

Context

Purpose of application

This application from UCL Great Ormond Street Institute of Child Health sets out the purpose of medical research that aims to determine why more babies are being diagnosed with congenital hypothyroidism with gland in situ (CH-GIS), and what health and development is like for children living with this condition. Applicants propose to link routine clinical and education data, and compare between children with CH-GIS, children with other forms of congenital hypothyroidism (CH), and unaffected children. Once linkage is complete, only pseudonymised data will be stored and analysed.

All children in the UK are offered screening for rare conditions at five days of age, one of which is CH, which without early detection and treatment can result in severe learning disability. Since the introduction of newborn screening 40 years ago, there has been an increase in the proportion of babies born with CH, particularly a type called CH-GIS. It is not clear why CH-GIS is becoming more common, or how it affects health, development and learning as children grow up. Study results will help inform parents and children about the health and education consequences of congenital CH-GIS, and clinicians about which treatment regimen is best for children's health and development. The results will also advise public health professionals about CH-GIS, and how it can be prevented.

The applicants are proposing two study designs within this application. A cohort study to investigate a change in the birth prevalence of CH and CH-GIS, which will link data for all children screened for a number of inborn conditions at the GOSH newborn screening laboratory between 1 January 2000 and 31 December 2020 (approximately 2.2 million children) (the GOSH NBS database) to the GOSH clinical database of diagnostic and treatment information for all children who screen positive for CH (the GOSH CH database). The applicants also plan to link the mothers to their children to indicate which babies are siblings in order to examine familial clustering of newborn TSH screening results. This dataset will be linked by NHS Digital to the Office for National Statistics (ONS) birth and deaths registration data.

The second study design is a case-control design which will link approximately 1800 children diagnosed with CH-GIS (from the GOSH CH database), will be linked by NHS Digital to Hospital Episode Statistics (HES), National Child Measurement Programme (NCMP), NHS Business Services Authority (NHSBSA) community dispensing data, and the National Pupil Database (NPD). Applicants will compare children's height and weight distribution as well as patterns of medicine dispensing in children with CH or CH-GIS compared to all children using aggregate data from NCMP and the NHSBSA dispensing database. Applicants will request these aggregate datasets from NHS Digital, for which support is not required. 15 controls per case will be selected from the HES part of the pseudonymous ECHILD database, matched on sex, month and year of birth and local authority, for which support is not required.

HES and NPD data are already linked for the ECHILD study and a pseudonymised version is held in the UCL Data Safe Haven (DSH), which applicants will be able to access with the pseudonymous HES-NPD linkage key provided by NHS Digital. NHS Digital will also provide the applicant with linked ONS data (to the whole NBS cohort), which will have all identifying information removed apart from the date of death, and the NBS identifier. NHS Digital will provide the applicant will a pseudonymous linked CH dataset, linked to NCMP and NHSBSA data.

GOSH link the datasets received from NHS Digital back to the NBS and CH linked dataset, modify the postcode to LSOA, and send the dataset to UCL Data Safe Haven for analysis. This flow also requires support as the date of birth and date of death will be contained in this file. UCL staff extract HES records (from the HES part of the linked-NPD-HES data) for children in CH database using the pseudonymised HES-NPD linkage key provided.

All the datasets will be pseudonymised for analysis. This will involve date of birth and date of death being modified to be less disclosive, and this will be performed within the UCL DSH by the named researcher. Full date of birth and full date of death will then be deleted.

The linked health data will be held in UCL's Data Safe Haven. Selected pseudonymous clinical variables from the linked health data will be securely transferred to the ONS SRS. The cohort will then be linked to the NPD part of the linked HES-NPD ECHILD data. The education outcomes will be analysed in the ONS SRS, according to DfE regulations.

The linkages are also below;

1. GOSH link two internal databases (NBS & CH) which will contain NBS cohort identifier
2. GOSH send identifiers, plus NBS cohort identifier to NHSD
3. NHSD link NBS data to ONS births and deaths registration data

4. NHSD link CH data only to NCMP data and NHSBSA data, and provide a HES-NPD ECHILD linkage key
5. Linked data sent back to GOSH, support required due to date of death, and GSH link to NBS-CH linked database using NBS cohort identifier
6. GOSH send linked dataset containing clinical information and date of birth and date of death, alongside NBS Cohort ID to UCL safehaven
7. UCL safehaven undertakes linkage from CH dataset to HES part of the linked NPD-HES data, using HES-NPD ECHILD linkage key.
8. Identifiers removed from dataset and deleted once in UCL DSH
9. Selected variables sent from UCL DSH to ONS SRS for analysis, and dataset linked to NPD part of the linked NPD-HES ECHILD data, using HES-NPD ECHILD linkage key.
10. Analysis undertaken in both ONS-SRS and UCL-DSH

A recommendation for class 2, 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 babies born in the North Thames region (including North London, Bedfordshire, Hertfordshire and Essex), whose newborn screening blood spot sample was tested at the Great Ormond Street Hospital (GOSH) newborn screening laboratory between 1 January 2000 and 31 December 2020 (approximately 2.2 million children) This will include approximately 1800 children with congenital hypothyroidism in the GOSH CH database. Age limit: 0 - 20 Years The children's mothers will also be included, however this will be less than 2.2 million mothers as some children will have the same mother

	Population based study: all 2.2 million Case-control study: 1800
Data sources	1. **Great Ormond Street Hospital for Children NHS Foundation Trust**: a. North Thames Newborn blood spot screening database– held at GOSH (GOSH NBS database). (**legal basis =Clinical database**) b. GOSH Congenital Hypothyroidism (CH) Database – held at GOSH (GOSH CH database). (**legal basis = Clinical database)** 2. **NHS Digital**: a. Hospital Episode Statistics (HES), Admitted Patient Care (HES-APC), Accident & Emergency/Emergency Care Dataset (HES A&E), Outpatient Data (HES-OPD): Note, HES records for both mother and baby will be linked and analysed for this study. linkage key for NPD-HES data obtained via NHS Digital, (the data controller), however the pseudonymous HES ECHILD database is retained in the UCL DSH b. Office of National Statistics Birth and Deaths registration data (ONS) (held by NHS Digital) c. National Child Measurement Programme (NCMP, held by NHS Digital; height and weight of primary school children at 4-5yr and 10-11yr) (**legal basis = nationally mandated**) d. NHS Business Service Authority (NHSBSA) community dispensing data (held by NHS Digital) 3. **Department for Education (DfE):** a. National Pupil Database (NPD), information on school performance and special educational needs) (**has alternate legal basis – not defined as confidential patient information**) – linkage key for NPD-HES data obtained via NHS Digital, DfE is the data controller for this dataset, however the pseudonymous NPD ECHILD database is retained in the ONS SRS
Identifiers required for linkage purposes	1. Name 2. NHS number (of child) 3. Mothers NHS number 4. Hospital ID 5. Date of Birth 6. Date of Death 7. Postcode (Unit level)

	8. Postcode histories 9. NBS Cohort identifier
Identifiers required for analysis purposes	No identifiers which have not been modified are required for analysis: identifiers will be deleted once they are modified. 1. Date of Birth - modified to analysis variable such as week of birth. This will be done by named researcher at UCL DSH 2. Date of Death - modified to month and year of death. Follow-up time from birth in days will also be calculated. This will be done by named researcher at UCL DSH 3. Post code (unit level) - used to map to Lower Super Output Areas. This will be done by the GOSH DRE team. 'Researchers' will not have access to full postcodes. 4. Gender 5. Ethnicity 6. Parent's country of birth, 7. Parent's occupation 8. NBS Cohort identifier 9. HES-NPD linkage key
Additional information	Linked health data is stored in the UCL Data safe haven. The linked NPD data will be kept in the ONS Secure Research Service.

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.

As previously, the Group believe the public interest for this research is very high, and the outcomes will have the potential to bring real benefit to this patient group, and potentially to others.

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**

Members agreed that seeking consent for undertaking these linkages was impracticable, given the applicant's justification that this will involve a large number of children and would introduce a significant risk of bias due to substantial potential non-response.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage between datasets, and the members were assured this could not be done in an alternative manner that was any less disclosive.

'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.

Patient notification materials have been provided by the applicant which will be placed on the Child Health Informatics Group (CHIG) website following support. As a response to the deferral, in addition to hosting the patient notifications and the privacy notice in the UCL ICH website, the patient notification will be available through the GOSH BRC website. The British Thyroid Foundation has agreed to put an update of the study and a link to the patient notification on their website and in their newsletter, which is going to be published in June.

The patient and public involvement group suggested other ways to communicate, and in response the applicant will;

- Develop a website about the project, hosted by UCL; where they propose to publish study summaries in other languages. (still in development)
- Tweet any updates from the project including new publications via the UCL GOS ICH Twitter account: https://twitter.com/UCLchildhealth and 'tag' other organizations involved in the project, including GOSH, British Thyroid Foundation (BTF), Genetic Alliance (GA), NIHR, to get a broad audience.
- Develop a video for the UCL GOS ICH YouTube channel, which was recently launched.

Additionally, parents are also informed via the PHE newborn screening leaflet https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby/introduction that blood spots and data from screening may be used in research, evaluation and audit and provides options for opt out from the use of data in research.

NHS digital will apply the national data opt out, and the patient notification lets parents and children know how to contact the study team at UCL in order to opt out if they wish, the UCL team will inform GOSH, and the patient is removed from the dataset being sent to NHS Digital.

The Members were content that the applicant had responded to the points raised in the deferral letter, by separating the information into a layered notification and separate privacy notice, exploring other websites, and discussing the notification strategy with a patient and public involvement group. It was noted that the documents explained the linkages clearly. The Committee also commented that the applicant should provide a lay explanation of what hypothyroidism is at the start of the notification materials.

The CAG were impressed with the proposed plans for communicating with a broader audience using social media, and were interested in the developments of the communication strategy described. They requested feedback at the time of the first 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.

As part of previous submission, the applicants have worked with the British Thyroid Foundation (BTF) in developing this research, and the CI has spoken to 7 parents whose children have CH about the study. The applicants have also spoken to People's Advisory Group and the Parents' and Carers' Advisory Group of the Great Ormond Street Hospital Biomedical Research Centre in September 2018. Presentations and feedback have been provided. All were very supportive of the research methodology, and were informed that the linkages would be unconsented.

The CAG were impressed with the previous patient and public involvement undertaken, and the only request in the deferral letter was to undertake further patient and public involvement with control mothers and children. Further meetings have been undertaken with the GOSH Young People's Advisory Group (YPAG) on 15th January 2021, which includes children and young people (some of whom have a long-term condition, and some do not). Applicants also met a number of representatives from rare disease charities (many of whom themselves are living with a rare disease or have family members who are affected) through the Genetic Alliance on 16th March 2021 to discuss data linkage for rare disease research. This further patient and public

involvement undertaken was with people who do not have CH, and all participants were supportive of the proposed methodology.

The Committee felt that the applicant had put in a lot of effort and taken the patient and public involvement seriously. It was extensive, and the applicants had clearly taken on comments provided by the patient and public involvement groups.

It was noted that although applicant has undertaken further patient and public involvement with groups of people who do not have CH, the deferral letter stated control mothers should be approached, and it does not seem that this has been undertaken. The members felt that further patient and public involvement should be undertaken with healthy mothers, to ensure the acceptability of using their confidential patient information without consent. However this is not required as further information before support can be provided, and instead is applied as a condition to feedback to the CAG six months from when support is in place.

Exit strategy

The study will only require support up until when the date of birth and date of death are modified and deleted from the dataset. The study will be undertaken over three years, and identifying information will be deleted before analysis. The applicant states identifiers will be deleted around 6 months after receiving the requested datasets, however it is hard to estimate at which time point they will receive the requested data.

The CAG were content with this clear exit strategy.

Confidentiality Advisory Group advice conclusion

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

In order to complete the processing of this application, please respond back to all of the request for further information, required to meet the standard conditions of support when available.

Request for further information

1. Please provide the REC favourable opinion of the amendment when this is available (see standard condition of support below).

2. Please provide evidence of NHS Digital review of the 19/20 DSPT for Great Ormond Street Hospital for Children NHS Foundation Trust (see standard condition of support below).

Specific conditions of support

The following sets out the specific conditions of support.

1. Please provide feedback at the time of the first annual review around the planned communication activities undertaken.

2. Please provide a lay explanation of hypothyroidism at the start of the notification materials, and provide an updated version to CAG, within one month from the date support is provided.

3. Please provide feedback surrounding further patient and public involvement undertaken with healthy mothers, to ensure the acceptability of using their confidential patient information without consent, within six months from the date support is provided.

4. Favourable opinion from a Research Ethics Committee. **Pending review regarding CAG related amendment.**

5. 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. **Pending:**

The NHS Digital **19/20** DSPT reviews for **University College London – School of Life and Medical Sciences (**EE133902-SLMS), **Office for National Statistics** (**ONS SRS)** (XDC), and **NHS Digital** (X26) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 25 May 2021)

The NHS Digital **19/20** DSPT review for **Great Ormond Street Hospital for Children NHS Foundation Trust** (RP4) is pending.

5. New applications – Research

a. 21/CAG/0064 - How are assessment tools and chronologies used by health and social care professionals in England to identify child neglect?

Context

Purpose of application

This application from Oxford Brookes University set out the purpose of medical research that seeks to establish how the assessment tools and chronologies undertaken by health visitors and social workers in England are used to identify child neglect.

Neglect is the most prevalent form of child maltreatment in England and its identification and assessment pose significant challenges to practitioners. The variability in practice and other factors may lead to differing outcomes for children, therefore the study aims to explore the factors that influence the use of child neglect assessment tools and chronologies by health visitors and social workers in England.

The project is comprised of two phases with only phase 1 to be considered by CAG. Phase 1 will explore the extent to which use of the child neglect assessment tools and chronologies impact on the quality of social work analysis and planning.

A recommendation for class 1, 2, 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. Full datasets and data flows are provided in the application form and relevant supporting documentation

Cohort	60 children aged 0 - 11 who were made subject to child protection plans for neglect between 01/04/2018 and 31/03/2019
Data sources	1. Children's Social Care (LA) case files (Liquidlogic electronic database for social work records- Oxfordshire County Council Local Authority Children's Services)

	2. NHS health visiting care notes (Carenotes electronic database for health visitor records- Oxford Health NHS Foundation Trust).
Identifiers required for identification of the cohort	1. Liquidlogic Children's social care System (LCS) number 2. NHS number 3. LCS status 4. Name 5. Date of birth
Identifiers required for linkage purposes	To link to Children's Social Care (LA) case files: 1. Liquidlogic Children's social care System (LCS) number 2. Unique study reference number To link to NHS health visiting care notes: 1. NHS number 2. Unique study reference number
Identifiers required for analysis purposes	1. Gender 2. Ethnicity 3. Age 4. Disability status
Additional information	The dataset for analysis can be considered pseudonymised as the Chief Investigator still retains the file containing the LCS, NHS Number and unique study reference numbers (R3), stored separately from the analysis file. Phase 2 of the activity is out of scope as it relates to healthcare professionals

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 Committee agreed that child

neglect is an important factor affecting child development and there was a clear public interest in this study.

Practicable alternatives

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

- **Feasibility of consent**

The applicants advised that the cohort involved in phase 1 of the project are children who have previously received social worker led intervention, and there is a strong likelihood that the families will not respond to a request to take part in the study. Any contact to seek consent may also cause distress to children who have experienced significant harm.

The CAG understood this reasoning; however members questioned whether some or all of the children were subject to Care Orders where the Local Authority might have parental responsibility. If this were the case then the question arose as to whether a feasible alternative would be for the local authority to give consent on behalf of the children? The applicant was asked to confirm if there are children in the cohort who would be in the care of the local authority and if the local authority could provide consent on their behalf as a possible practicable alternative for this sub-cohort.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage. The CAG agreed that the use of specified identifiers was necessary to enable the linkages however they queried the length of retention of the key, which is detailed in the section below on exit strategy.

'Patient Notification' and mechanism for managing dissent

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

The applicant confirmed that as the study cohort included children who had suffered from neglect and their carers, it had been determined that the benefit of notifying the study population was outweighed by the potential negative impact or risk to participants. Reference was made to a Data Protection Impact Assessment (DPIA) and the conclusion that a specific privacy notice was not required as the organisation's generic Privacy Notice covered this work already.

The applicant also advised that it is commonly understood by service users/ families accessing services from children's social care, that information sharing will occur to ensure the safety of children, provide the most suitable support and/or services, and for the purpose of service/ practice evaluation and auditing. It is common practice for professionals to explain this to service users at the start of their working relationship and at several other points along the process. At the point of first contact with Children's Services, families are provided with an information pack which contains detailed information regarding information sharing situations and a copy of the organisation's generic Privacy Notice. The applicants have therefore advised that they are not undertaking patient notification. Consequently, it is unclear how people can register dissent.

The CAG carefully considered the reasoning provided by the applicant for not developing a notification and dissent strategy In reviewing the current information provided to service users, Members noted that the wording of the privacy notice implied consent would be obtained for purposes outside of direct care.

In addition, NICE guideline NG76: (Child abuse and neglect) Paragraph 1.1.10 sets out the basic principles for work with parents and carers of neglected children. Guidance includes keeping them informed, including explaining what information has been shared and with whom, and being clear about the legal context in which your involvement with them is taking place. Researchers are not explicitly listed in this clinical guideline, however since the implicit agreement between practitioners and parents that information will be shared is cited by the applicant as the basis for using these data without consent, members felt the principles which inform that agreement should be taken into account.

The Members felt therefore that to ensure transparency, information on the activity should be developed that includes an opt out option. This should be displayed somewhere accessible so that the relevant cohort may see it such as the university website, the LA website, and the Trust website. Guidance should be taken from patient and public involvement groups regarding notification and opt out methods.

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 application confirmed consultation had taken place with social care and health practitioners at local Neglect Practitioners' Forum and Neglect Strategy meetings and with the local county council and NHS trusts.

Patient and public involvement had not been carried out in relation to this activity on the basis it would be extremely difficult to ask a representative group about this study, as the cohort is neglected children, and any parents of these children are under investigation and are not an appropriate group to try to contact.

The Members considered the reasons for not undertaking any patient and public involvement in this extremely sensitive cohort, however it was felt that a representative group must be consulted regarding this application. It was suggested that the applicant could reach out to charities such as The charity for children in care and young care leavers (becomecharity.org.uk) or NSPCC (The UK children's charity). These charities should be able to help connect the applicant to people who may have experience of neglect, including adults with relevant experience and children, and the applicant should present the study to a group of people for their thoughts. The CAG recommended that applicants should consult both charities and additionally any other charities concerned with the welfare of children in this circumstance. It was commented that Barnardos provides a Guardian ad Litem service to represent children in court proceedings, who might also be able to provide patient and public involvement input.

Specifically the Committee would like to see a patient and public involvement opinion regarding the acceptability of this use of confidential patient information without consent. The members also advised that the applicant should seek a patient and public involvement opinion regarding how to implement a notification and opt out strategy.

Exit strategy

On completion of the project, planned to end in late 2022, the applicant will delete the decoding document which will render the dataset fully anonymised. Support will be required until the applicant deletes this key.

The Committee queried why the key between identifying information and unique reference numbers is required to be retained by the Chief Investigator (CI) throughout analysis, and suggested that maybe this document could be retained by the local authority and the NHS Trust, which would not require support. The applicant is asked to provide justification to retain the decoding document (R3) after the pseudonymous dataset has been extracted, or consider if the decoding document (R3) could be retained by the local authority and NHS Trust.

Home working

Data linkage between R3 and Liquidlogic, the electronic Local Authority Children's social care database, will be undertaken by the CI at home using the LCS number, via an Oxford Brookes University laptop. The Members assumed that this would be undertaken in a secure home set up with appropriate organisational safeguards, for example encrypted devices and communications. However the Committee would like the applicant to confirm that the home working set up is secure, so they can be reassured the appropriate safeguards are in place.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. The applicant is to consider the possibility of the local authority providing consent on behalf of children operating under a Care Order.

2. A notification method that provides Information on the activity as described above, including an opt out option is to be developed and provided.

3. Patient and public involvement in a representative group of adults with relevant experience and children to be undertaken, potentially using links provided by charities as described in this letter. The Members wish to see a patient and public involvement opinion regarding the acceptability of this use of confidential patient information without consent, and regarding implement of a notification and opt out strategy.

4. Please provide justification for the CI to retain the decoding document (R3) after the pseudonymous dataset has been extracted. Applicant to consider if the decoding document (R3) could be retained by the local authority and NHS Trust.

5. Provide details of the organisational and technical arrangements in place around the home working arrangements that ensure information is processed securely.

Specific conditions of support

The following sets out the specific conditions of support.

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

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

   Pending:
   The NHS Digital **19/20** DSPT reviews for **Oxford Health NHS Foundation Trust** (RNU) and **Oxfordshire County Council, Local Authority Children's Services** (608) were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 27 May 2021)

   The NHS Digital **20/21** DSPT review for **The Faculty of Health and Life Sciences, Oxford Brookes University** (EE133864-FHLS) was underway, but pending. A 19/20 DSPT review is unavailable.

b. 21/CAG/0070 - The DAMPen-D study: Improving the Detection, Assessment, Management, and Prevention of Delirium in Hospices - Co-design and feasibility study of a flexible and scalable implementation strategy to deliver guideline-adherent delirium care

Context

Purpose of application

This application from the University of Hull set out the purpose of medical research that seeks to establish whether it is feasible to collect sufficient outcome data, explanatory process data, and cost data, in a future effectiveness evaluative study in palliative care settings.

It is common for people to suffer from acute confusion, or delirium, towards the end of their life, which can be distressing for those with delirium, and their friends, family and carers. Treating delirium can also cause anxiety and stress for the health professionals who are trying to manage the delirium effectively. The applicants noted the importance of improving how delirium is assessed, prevented and managed within hospices. Guidelines for improving delirium care have been issued by the National Institute for Health & Care Excellence, the Scottish Intercollegiate Guidelines Network, and the Australian Commission on Safety & Quality in Health Care, however research shows that less than half of palliative care doctors use delirium guidelines. Delirium screening tools are infrequently used, yet there is no research about how to improve the implementation of delirium guidelines and tools in day-to-day practice. The applicants seek to address this by conducting a feasibility study to assess the usefulness of the CLECC-Pal implementation plan in day-to-day use of guideline-recommended clinical

care, and whether, under these circumstances, the number of delirium days suffered by patients is reduced in a cost-effective manner. The applicants will also be assessing whether a larger-scale study can be run. The study is comprised of 3 work packages. Work Package 1 involves engagement with stakeholders. Work Package 3 is a process evaluation, where staff and volunteers will take part in surveys. Work Packages 1 and 3 are outside the scope of REC review and the support sought under Regulation 5.

The study will be conducted in three non-NHS inpatient hospice units in Yorkshire. The hospices will be supported by the study team in using the CLECC-Pal plan to implement guideline recommended delirium care over a minimum of 12 weeks. At sites 1 and 2, paper case records will be accessed by the research team. The hospice staff will identify 50 consecutive patients who were admitted to the hospice before the CLECC-Pal was used in the hospice. The researcher will then access the patient records to extract anonymised data. Each documented case of delirium will be assigned a unique identifier number by the researcher (the study ID), which will be used internally by the research team to identify individual episodes of delirium. This unique identifier will not be used to link the extracted data back to the clinical records, as no key is retained. The same process will be repeated for 12 weeks after the implementation of the CLECC-Pal at the site. Site 3 has electronic patient records only. This computer will be located in a GP practice in Hull. As at sites 1 and 2, hospice staff will identify 50 consecutive patient records preceding the date CLECC-Pal (the intervention) was introduced to the hospice. Hospice staff will email the patients NHS number to the researcher via secure NHS email, in order for the researcher to be able to identify the patient on SystmOne. The researcher will then access the patient records on SystmOne remotely via a secure NHS GP surgery computer located at a GP surgery in Hull and extract an anonymised dataset. Only pseudonymised data will be uploaded to the study records, on the University of Hull laptop, and this can be considered anonymous to the applicants.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over who are receiving inpatient palliative care at the three participating hospices

	(50 consecutive patients from each hospice, over 2 time periods, so 100 total per site.)
Data sources	1. Paper records held at 2 participating hospices • Dove House Hospice, Hull • St Leonards Hospice, York 2. Electronic records held at the third participating hospice: • Marie Cure, Bradford, which will be accessed on University of Hull encrypted laptop at James Alexander Family practice, Hull
Identifiers required for data extraction for paper records at 2 participating hospices	1. Age 2. Sex 3. Ethnicity 4. Unit level Postcode (converted to multiple deprivation index at extraction) 5. Unique study ID – allocated by the researcher at point of extraction 6. Patients medical records will be viewed
Identifiers required for data extraction from SystmOne at 1 participating hospices	1. NHS number (in order to identify patient on SystmOne) 2. Age 3. Sex 4. Ethnicity 5. Unit level Postcode (converted to multiple deprivation index at extraction) 6. Unique study ID – allocated by the researcher at point of extraction 7. Patients medical records will be viewed
Identifiers required for analysis purposes	1. Age 2. Sex 3. Ethnicity 4. Unique study ID This can be considered anonymous to the researchers.

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 noted that this was an important study in a sensitive area, and agreed there was a strong public interest.

Practicable alternatives

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

- **Feasibility of consent**

The applicants explained that consecutive samples of case notes are required, and that requesting consent or assent would introduce sever bias to the cohort, and the sample may be under representative of people with delirium. The applicant has also reasoned that gatekeeping bias is well documented in hospice research, which would be avoided if consent was not sought. The patient and public involvement undertaken also showed a very strong opinion that applicants should avoid having to approach patients or representatives for consent/consultee agreement.

The Committee accepted this justification.

- **Use of anonymised/pseudonymised data**

The research team require access to confidential patient information in order to extract an anonymised dataset for use in analysis. The Committee were content that this could not be undertaken in a less disclosive manner.

'Patient Notification' and mechanism for managing dissent

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

A poster was provided with the application. This included information about the study and email and telephone contacts for patients, or their representatives, to dissent. The applicants advised that they had developed the wording and format of these with their Public Involvement Group members. The poster gave patients, and their representatives, email and telephone contacts in order to opt-out. Hospice staff at each study site will conduct an opt-out check to

identify any case records where the patient and/or their family have declined researcher access to their case notes.

The CAG were content with the opt out provided, and broadly content with the poster notification. The Members commented that the patient and public involvement had advised a poster and an A5 leaflet, and only a poster had been provided. However it was understood from the application that the poster would be turned into the A5 leaflet and included as a package insert.

It was felt that the notification was clear, and good overall, however the Members did comment on two parts of the poster. Firstly, they noted that use of the word anonymous is not lay friendly, and perhaps it should be explained which data items will be collected rather than labelling it anonymous.

It was also commented that the statement '*the researcher is approved to record anonymous information'* is not quite accurate. The CAG felt it should be made clearer that the researcher does in fact has access to confidential patient information within the notes, in order to extract the dataset.

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 held two half-day meetings with four public involvement group members to discuss the project. All members had experience of a loved ones suffering with delirium. The group agreed that one member would join the research project as a collaborator (contributing to workshop facilitation, materials for ethical approval, and data analysis), one would take up a role on the steering group, and all four would participate in the reference group.

The Public Involvement Group members were asked for their views on whether patients and/or their consultees should be approached for consent/agreement for either clinical assessment or case record data extraction. The members agreed that the benefit outweighed the risk and that seeking consent would potentially be distressing to the patients and their representatives. The issue of accessing confidential patient data without consent has been explained and supported by the group.

The Committee were impressed by the level of patient and public involvement undertaken, commenting it was very strong, and the applicant was clearly very engaged. The applicants had discussed the correct subject matter with interested parties, and listened to the feedback carefully. The CAG commended the applicant on the excellent patient and public involvement.

Exit strategy

Patient data will be anonymised at the point of extraction. The CAG were content with this exit strategy.

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

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

Request for further information

1. Please provide the favourable opinion from the REC when available (standard condition of support, see below).

2. Please provide an updated patient notification which contains a lay explanation of the term anonymous, and is explicit in describing the access the researcher is permitted to have regarding medical notes.

Specific conditions of support

The following sets out the specific conditions of support.

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

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

   Confirmed:-
   Security assurances are required for the 5 sites where processing of confidential patient information will take place. Support will be based on confirmation that the DSPT at the site will be complied with. However, as this is 5 or more organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.

The organisations involved are:
- University of Hull - Hull Health Trials Unit (EE133824-HHTU)
- Dove House Hospice, Hull

- St Leonards Hospice, York
- Marie Cure, Bradford
- James Alexander Family practice, Hull

6. Minutes of previous meetings

The minutes for the following CAG meetings have been ratified via correspondence and are notified for information at this meeting:

Sub-committee meetings: January 2021, February 2021, March 2021

7. Any other business

No other business was raised.

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

Signed – Chair	Date
Minutes signed off via correspondence by Dr Will Bernal and Dr Murat Soncul, CAG Alternate Vice Chairs	12/10/2021

Signed – Confidentiality Advice Team	Date
Katy Cassidy	12/10/2021