Health Research Authority
2 Redman Place
Stratford
London
E20 1JQ

Tel: 020 7104 8100
Email: cag@hra.nhs.uk

28 January 2021

Professor Alastair Sutcliffe
Professor of General Paediatrics
30 Guilford Street
London
WC1N 3EH

Dear Professor Sutcliffe

Application title:	**Childhood outcomes after perinatal brain injury: a population-based linkage study**
CAG reference:	**20/CAG/0107**
IRAS project ID:	**280738**
REC reference:	**20/LO/1023**

Thank you for submitting a **research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

Supported applications allow the controller(s) of the relevant data sources, if they wish, to provide specified information to the applicant for the purposes of the relevant activity without being in breach of the common law duty of confidence. Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 17 September 2020.

This outcome should be read in conjunction with the provisional support letter dated 29 September 2020.

Health Research Authority decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application, to allow the disclosure of confidential patient information for patients in cohorts 1 and 2 from The Neonatal Data Analysis Unit (NDAU) at Chelsea & Westminster Hospital NHS Foundation trust to NHS Digital for the purposes of the linkage to NHS Digital held datasets, PDS, HES, ONS and MHSD, and for the disclosure of confidential patient information for patients in all 3 cohorts from NHS Digital to the Department of Education for linkage to the National Pupil Database, is conditionally supported, subject to compliance with the standard and specific conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

Purpose of application

This application from University College London Great Ormond Street Institute of Child Health (UCL GOS ICH) set out the purpose of medical research that aims to conduct a population-based matched cohort study of children born in England 2008-2020, to investigate differences in long-term health, mortality and educational outcomes in children with perinatal brain injury compared to those without brain injury. The primary outcome for the study is neurodisability at 2, 5 and 12 years, and secondary outcomes include all-cause mortality, mental health and behavioural conditions, chronic conditions, academic attainment, and special-educational needs.

Over 3400 babies born in England suffer a brain injury every year. Neonatal brain injuries around the time of birth can have devastating lifelong consequences for children, parents and society as a whole. There have been major advances in healthcare that mean more babies with brain injuries survive, but the long-term effects of these injuries are not well-known. Currently, it is not known which infants suffering perinatal brain injury should be followed up, how long they should be followed up for, what conditions they are likely to develop or what additional support they may need from the NHS, social care, or schools in terms of their health, development and education. This study has been created with the aim of gathering information on the prognosis and quality of life after a neonatal brain injury in order to assist staff in conducting family-centred discussions about what the future may hold and help shape health and educational services.

Three cohorts will be included in the study. Cohort 1 will include all newborns with a perinatal brain injury who were born in England between 2008 and 2020. Cohort 2 will be a per-term control group and will contain a 1:1 propensity score matched comparator group for babies born before 34 weeks gestation. NHS Digital will match the cohort using Office of National Statistics (ONS) data in order to create Cohort 3, a full-term control group.

The National Neonatal Research Data (NNRD) captures data items, including date of birth, postcode, and infant NHS number, but does not reliably hold children's' registered names. Additionally, the NNRD contains the infants' postcodes at birth, but does not capture postcode changes throughout childhood. Therefore, the NNRD cohorts 1&2 will be linked to the NHS Digital Personal Demographics Service (PDS), using NHS number, date of birth, gender and postcode at birth: to identify registered forename and surname, and postcodes changes.

NHS Digital will then link all 3 cohorts to 3 datasets held at NHS Digital; Hospital Episode Statistics (HES), ONS mortality data, Mental Health Services Dataset (MHSD). NHS Digital will send identifiers to the Department for Education (DfE) for linkage with the National Pupil Database (NPD). The Neonatal Data Analysis Unit will create a pseudonymous file containing the neonatal care data for cohort 1 & 2. Cohort 3 will be identified by NHS Digital. Cohorts 1, 2 & 3 will be linked at NHS Digital and the Department for Education, and a pseudonymous file will be created for each linked dataset. The 5 pseudonymised datasets will then be securely transferred to ONS Secure Research Service (SRS), where they will be cleaned and merged. Data within the SRS will retain only an anonymous unique identifier - they key to which will only be held at the Department for Education and NHS Digital for their respective linkages. The data generated by the study will be analysed in the ONS secure research service. It will either be accessed through one of the ONS safe rooms of via a UCL SRS remote connectivity site.

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	• Cohort 1: All newborns with perinatal brain injury, born in England between 1 January 2008 to 31 December 2020 (approximately 43,582) • Cohort 2: Pre-term control group: Propensity score matched comparator group for those born <34 weeks gestation (1:1) to control infants using propensity score matching to account for confounders, born in England between 2008-2020 (approximately 16, 175) • Cohort 3: term control group: matched term population for the infants ≥34 weeks gestation in cohort 1, identified by NHS Digital using the covariates below, born in England between 2008-2020 (using a 1:3 algorithm; approximately 82, 221).
Data sources	1. National Neonatal Research Database controlled by the Neonatal Data Analysis Unit (NDAU) 2. ONS, PDS, HES and MHSD datasets, held by NHS Digital 3. National Pupil Database, held by the Department for Education
Identifiers required for linkage purposes	For linkage of cohort 1&2 with NHS Digital (PDS) data: 1. NHS number 2. Date of birth

	3. Postcode at birth 4. Gender From these provided identifiers NHS Digital PDS will identify infant forename, surname and postcodes over time, which will validate linkages and be sent to DfE. For linkage of cohort 1,2 & 3 with NHS Digital: HES, ONS, MHSD data: 1. NHS number 2. Infant Forename 3. Infant Surname 4. Date of birth 5. Gender For linkage of cohort 1, 2 & 3 with National Pupil Database NHS Digital will send the following identifiers to the DfE: 1. Infant Forename 2. Infant Surname 3. Date of birth 4. Gender 5. Postcode at birth, 6. Most recent postcode Any additional childhood postcodes
Identifiers required for analysis purposes	No identifiers will be retained for analysis
Additional information	For NHS Digital to identify cohort 3 the following non identifiable data from the infants ≥34 weeks gestation in cohort 1 is required: 1. Birthweight 2. Year of birth 3. Multiplicity 4. Gender 5. Lower layer Super Output Areas (LSOA) The ONS SRS will receive 5 pseudonymised files: file 1 from the NNRD containing neonatal care data for cohorts 1 and 2; files 2-4 containing survival, health and mental health data for cohorts 1-3; and file 5 containing educational outcomes data for cohorts 1-3. None of these will contain personal identifiers. The data generated by the study will be analysed in the ONS secure research service. It will either be access through one of the ONS safe rooms of via a UCL SRS remote connectivity site

Confidentiality Advisory Group advice

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

1. **The applicants are to collaborate with the NDAU to design and implement a study-specific dissent mechanism. Details of the dissent mechanism are to be provided in the patient notification leaflet.**

The applicants explained that they had worked with the NDAU to provide further clarity. Dissent from data sharing via the NDAU is possible via three existing mechanisms. All parents with an infant admitted to a neonatal unit are offered a leaflet that includes details about the NDAU. This leaflet contains an e-mail contact for parents wishing to opt-out of data sharing. This email will also be included in the study patient notification leaflet. Parents can also opt-out via their local neonatal unit, in such instances their infant's data would not be submitted to the NDAU. Additionally, at a neonatal unit level, all units are informed about individual studies and individual units may opt out of data sharing for specific studies. This information was included in the patient notification leaflet for this study. The CAG noted this information and raised no further queries.

2. **The patient notification leaflet is to be made available on the websites for BLISS and the Meningitis Research Foundation, and other appropriate websites. The leaflet needs to be displayed for 6-8 weeks before the data extraction and linkage begins, to give patients sufficient time to register dissent.**

The applicant advised that a summary of the study will be displayed on both the BLISS and Meningitis Research Foundation websites at least 6 weeks prior to the data extraction. This summary will include a clear link to the patient notification leaflet (published on the UCL website). Both BLISS and Meningitis Research Foundation will also publicise the patient notification 6 weeks before data extraction via their social media platforms to raise awareness of the study. This will give parents sufficient time to register dissent. The CAG noted this information and raised no further queries.

3. **The patient notification leaflet is to be reviewed by a patient group and revised in line with any suggestions made.**

A patient notification leaflet, which had been reviewed by the Great Ormond Street Hospital Parent Advisory Committee and revised in response to their suggestions, was provided. The CAG noted this information and raised no further queries.

4. **Clarify why the data linkage will not be completed until August 2022.**

The study will not commence until September 2021. The applicants anticipated that the data linkage will be completed within 6 months, by March 2021, however the linkage to the NPD cannot begin until the NHS Digital linkage has been undertaken. The applicants had therefore been flexible with the estimated timeline to account for potential delays. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Feedback from the planned continuing engagement is to be provided when submitting annual reviews to the CAG.

2. The patient information leaflet needs to be revised to include telephone and postal contact details, as well as email.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 25 September 2020.**

4. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **The NHS Digital DSPT review for the following organisations were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 18 September 2020)**

    - **University College London – School of Life and Medical Sciences (standards met for DSPT 2018/19)**
    - **Office for National Statistics (standards met for DSPT 2019/20)**
    - **Department for Education (standards met for DSPT 2019/20)**
    - **NHS Digital (standards met for DSPT 2018/19)**
    - **Chelsea & Westminster Hospital NHS Foundation Trust (standards met for DSPT 2018/19)**

As the above conditions have been accepted and met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Application maintenance

Annual review

Please note that this legal support is subject to submission of an annual review report, for the duration of support, to show that the minimal amount of patient information is being processed and support is still necessary, how you have met the conditions or report plans, any public benefits that have arisen and action towards meeting them. It is also your responsibility to submit this report every 12 months for the entire duration that confidential patient information is being processed without consent.

The next annual review should be provided no later than **28 January 2022** and preferably 4 weeks before this date. Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support. Submission of an annual review in line with this schedule remains necessary even where there has been a delay to the commencement of the supported activity, or a halt in data processing. Please ensure you review the HRA website to ensure you are completing the most up to date 'section 251' annual review form as these may change.

For an annual review to be valid, there must also be evidence that the relevant DSPT submission(s) for organisations processing confidential patient information without consent are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the CAG annual review submission date to check they have reviewed the relevant DSPTs and have confirmed these are satisfactory.

Register of Approved Applications

All supported applications to process confidential patient information without consent are listed in the published 'Register of Approved Applications'. It is a statutory requirement for the Register to be published and it is available on the CAG section of the Health Research Authority website. It contains applicant contact details, a summary of the research and other pertinent points.

This Register is used by controllers to check whether support is in place.

Changes to the application

The application and relevant documents set out the scope of the support which is in place for the application activity and any relevant restrictions around this.

Any amendments which are made to the scope of this support, including but not limited to, purpose, data flows, data sources, items of confidential patient information and processors, require submission of a formal amendment to the application. Changes to processors will require evidence of satisfactory DSPT submission. The amendment form can be found in the Confidentiality Advisory Group pages on the Health Research Authority website.

Support for any submitted amendment would not come into effect until a positive outcome letter has been issued.

Changes to the controller

Amendments which involve a change to the named controller for the application activity require the submission of a new and signed CAG application form and supporting documentation to support the application amendment. This is necessary to ensure that the application held on file appropriately reflects the organisation taking responsibility for the manner and purpose of data processing within the application, and that the legal support in place is related to the correct legal entity.

Applicants are advised to make contact with the Confidentiality Advice Team to discuss a change in controllership for an existing application in sufficient time ahead of the transfer of project responsibility to discuss the submission process timings.

Further information and relevant forms to amend the support is available on the HRA website.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [CAG_Form_snapshot]		07 May 2020
Covering letter on headed paper [IRAS cover letter v1]	1	
Other [Data flow diagram v4.1]	4.1	16 July 2020
Other [E-mail of support from DfE]		
Other [HDEC-Peer-Review-Template_BC]		
Other [BLISS Letter of support]		
Other [MRF letter of support]		
Other [NHS Digital letter of support]		

Other [Rees HDEC-Peer-Review-Template JO]		
Research protocol or project proposal [protocol v 1 (IRAS)]	1	16 July 2020
Written recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [HRA letter of recommendation]		
RH Patient notification v1.4	1.4	
Response to CAG		

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item are listed below.

There were no declarations of interest in relation to this item.

User Feedback

The Health Research Authority is continually striving to provide a high-quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R & D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

With the Group's best wishes for the success of this project.

Yours sincerely

Kathleen Cassidy
Confidentiality Advisor

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Included: List of members who considered application
Standard conditions of support

Copy to: westlondon.rec@hra.nhs.uk
approvals@hra.nhs.uk

Confidentiality Advisory Group meeting attendance
17 September 2020

Members present:

Name	
Dr Malcolm Booth	CAG member
Ms Sophie Brannan	CAG member
Dr Liliane Field	CAG member
Dr Lorna Fraser	CAG member
Mr. Myer Glickman	CAG member
Dr Simon Kolstoe	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Senior Confidentiality Advisor/Service Manager

NHS
Health Research Authority

Standard conditions of support

Support to process the specified confidential patient information without consent, given by the Health Research Authority, is subject to compliance with the following standard conditions of support.

The applicant and those processing the information under the terms of the support will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.

4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities and are acting in compliance with the application detail.

6. Activities must be compliant with the General Data Protection Regulation and Data Protection Act 2018.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.

10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.

11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken/to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.