Health Research Authority

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29 September 2020 – reissued

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Dear Dr Sarah Seaton

Application title:	**Understanding the epidemiology in the transition from neonatal to paediatric care: a data linkage study**
CAG reference:	**20/CAG/0110**
IRAS project ID:	**283808**
REC reference:	**20/EE/0220**

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 precedent set CAG meeting held on 11 September 2020. The application was considered via the Precedent Set process under criteria 4 - Time limited access to undertake record linkage/validation and to anonymise the data.

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:

The application, to allow:

- The disclosure of confidential patient information (NHS number, sex, postcode, date of birth and unique ID) from National Neonatal Research Database

(NNRD) and Paediatric Intensive Care Audit Network (PICANet) to NHS Digital,

- The disclosure of confidential patient information (NHS number only) from National Neonatal Research Database (NNRD) and Paediatric Intensive Care Audit Network (PICANet) to NHS Wales Informatics Service (NWIS),
- Linkage of the above datasets together, and further linkage with Hospital Episode Statistics (HES) and Mortality data (Office for National Statistics - ONS) held by NHS Digital, and Patient Episode Database for Wales (PEDW) data, held by NWIS.

is conditionally supported, subject to compliance with the standard and specific conditions of approval outlined below.

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 of Leicester sets out the purpose of medical research that aims to describe and understand the epidemiology of children who receive neonatal and/or paediatric care by linking together information about the care they have received. The aim is to understand which children who receive neonatal care also go on to need paediatric care, how this affects service providers, and how patients and families can be best supported.

Following birth, around one in seven babies are admitted for specialist neonatal care in the UK. Admission rates to neonatal care have increased, partly due to improved survival of the most vulnerable babies, particularly those born very prematurely or those with serious health problems. More of these babies now survive, but the impact of their health and the care received immediately after birth can be lifelong. There has also been an increase in admissions to Paediatric Intensive Care Units (PICU) in the last ten to fifteen years. Many admissions relate to children who received neonatal care immediately after birth, although the exact number is not known. Very little is known about what happens between neonatal and paediatric care including which children are likely to experience both types of care, and how clinical services, parents and professionals manage the transition.

This study will use information from two established databases, both of which have a legal basis to collect confidential patient information under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002: the National Neonatal Research Database (NNRD) (CAG ref: ECC 8-05(f) / 2010) and the Paediatric Intensive Care Audit Network (PICANet) (CAG ref: PIAG 4-07(c)/2002). The NNRD captures information about all babies admitted for neonatal care after birth. PICANet captures information related to referrals, transports and admissions to PICU. Applicants will focus on care received in the first two years of life but for those children who were also subsequently admitted in later years, information relating to later admissions will also be received.

Each database will provide the identifiers from their datasets to NHS Digital, who will link the 2 data sets together as a trusted third party. NHS Digital will establish three datasets - those only in the NNRD, those only in PICANet, and those common to both datasets. NHS Digital will then link these data to Hospital Episodes Statistics (HES) and mortality data (ONS). The datasets from NNRD and PICANet will also be linked to Patient Episode Database for Wales (PEDW) by NHS Wales Informatics Service (NWIS), to collect information about admissions in Wales. The pseudonymised linked datasets will be transferred from NHS Digital and NWIS to the researchers at University of Leicester. Pseudonymised clinical datasets will also be transferred directly from the NNRD/PICANet to the research team at the University of Leicester, containing data related to demographics, care, treatment and outcomes. The researchers will then link the clinical datasets to the pseudonymised linked (to HES, ONS, and PEDW) NNRD/PICANet datasets, using a pseudonymised identifier.

All data provided to the team at the University of Leicester will be pseudonymised. The pseudonymised data can only be linked to personal data by NHS Digital or the teams at the NNRD or PICANet. The University of Leicester cannot link back to any personal data and will not hold any of the primary datasets.

A recommendation for class 4 & 6 support was requested to cover 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 admitted to neonatal care in England and Wales from 1 January 2013 to 31 December 2018 (~480,000 babies) and all children aged <2 years admitted to PICU from 1 January 2013 to 31 December 2020 (~ 80,000 admissions).
Data sources	1. National Neonatal Research Database (NNRD): (Chelsea & Westminster Hospital NHS Foundation Trust) • Information about all babies admitted for neonatal care. 2. Paediatric Intensive Care Audit Network (PICANet): (University of Leeds) • Information about children aged <2 years admitted for paediatric intensive care, • and Information about children who were subsequently admitted after age two years for relevant children. 3. NHS Digital: • Mortality data (Office for National Statistics - ONS) • Hospital Episode Statistics (HES) data 4. NHS Wales Informatics Service (NWIS): • Patient Episode Database for Wales (PEDW) data
Identifiers required for	1. NHS Digital will complete linkage using:

linkage purposes	• NHS number • Date of birth • Sex • Postcode 2. The NHS Wales Informatics Service will complete the linkage using only NHS number
Identifiers required for analysis purposes	1. Age 2. Sex 3. Ethnicity 4. Date of death (modified to age of child at time of death)
Additional information	All records transferred to NHS Digital will include a pseudo-anonymised identifier to allow linkage back to the clinical data by the team at the University of Leicester. No clinical data will be transferred from the NNRD or PICANet to NHS Digital.

Confidentiality Advisory Group advice

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

Public interest

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

The CAG agreed that the application was in the public interest and has a clear medical purpose.

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 reason that consent is not practicable or appropriate for a number of reasons, including that opt-out options already exist with the NNRD and PICANet; the size of the cohort (up to 560,000), the emotional burden on parents to be contacted potentially years after the admission, and the inability for the research team to ensure correct contact information.

The CAG agreed with the rationale given for not seeking consent.

- Use of anonymised/pseudonymised data

The applicants require confidential patient information for linkage from NNRD to PICANet, and also for linkage from these 2 datasets to HES, ONS and PEDW data.

The Group noted that the applicants plan to use existing legal databases and their protocol follows a well established model of using NHS Digital as a trusted third party to perform the linkages, and release pseudonymised data back to the researchers. As such, the CAG were content that this could not be performed in any other way that would reduce the use of identifiers.

'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 objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants detailed that information letters outlining the study will be sent to Lead Clinicians in all neonatal units and paediatric intensive care units. The REC favourable opinion of the NNRD offers individual neonatal units the opportunity to opt-out of research projects. This is an established approach used by the team who manage the NNRD. Applicants also mention potentially creating a study poster, and have provided a study privacy notice will be placed on the University of Leicester website. The applicants commented that further Information about the project will also be made available online, on the PICANet and NNRD websites.

It was noted by the CAG that for this study patient notification will be difficult - as posters are unlikely to be seen by parents of babies included in the cohort and are discouraged at present because of Covid-19. The Group commented that the information letters to be sent to the clinical units involved are not a method of patient notification, as they would not be notifying the cohort of patients who are involved, and it was mentioned that the letters do not include any request to promote the study.

The CAG accepted that online notification is likely the only appropriate method in this case; However, the study privacy notice is not sufficient on its own. Although the content is appropriate, it is not likely to be seen by anyone involved. It is likely that NNRD and PICANet websites, alongside the University of Leicester website are the most appropriate way of informing those involved. Members noted that no project specific notification material has been provided with the application that details a study specific opt out (see below). However the Group are content to support the application on condition that the applicants provide the patient notification material, including a project specific opt out, within three months from the date of this outcome letter.

Applicants have not provided a study specific opt out mechanism and have mentioned that they plan to direct parents to NNRD and PICANet websites if they wish to withdraw their child's data. As mentioned above, all neonatal units will be written to with information about the study and offered the opportunity to opt-out. This is an established process. PICANet has approval to be used for research, and all PICUs will receive information about this study. Applicants have confirmed that the national data opt out will be applied.

The CAG considered that there should be a study specific opt out mechanism available on the NNRD and PICANet websites. Although they agreed it was unlikely

that a parent would want to only opt out of the study rather than the particular database, the option still needs to be provided. The Group additionally commented that it is not appropriate for the applicant to encourage opting out of the NNRD and PICANet entirely, when a parent may only object to this particular study. However, the CAG are content to support the application on condition that the study specific dissent mechanism is provided within three months from the date of this outcome letter.

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 advised that parents with experience of a child having received neonatal care helped to develop this research project, that the idea for the study was triggered from a PPI meeting, and parents will continue to be involved throughout. A parent advisory group will be established for the purposes of this study. However, the CAG were not clear if applicants have tested the acceptability of using patient identifiable data in this specific project without patient consent, despite a response to a query regarding this.

The CAG agree that the parent advisory group sounds supportive, but feel they require some more information regarding who was involved in this, how many members there are, whether it was ongoing and how it had assisted the project thinking. The CAG especially wish to hear feedback surrounding whether they have specifically considered the use of confidential data without consent. However members are content to support the application on condition that the applicants provide a report detailing that the use of confidential patient information without consent was discussed with the patient group, their response to this and how many patients were involved in this discussion is provided within three months from the date of this outcome letter. The CAG also wish, at the first annual review, to see a report on the ongoing activities of the parent advisory group.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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.

In order to complete the processing of this application, please respond back to all of the actions required to meet the specific conditions of support where indicated.

Specific conditions of support

1. The patient notification text, to be displayed on the University of Leicester, NNRD and PICANet websites, to be provided to CAG within three months from the date of this letter. This notification should include clear details for a study specific dissenting mechanism.

2. Provide a report, within three months from the date of this letter, detailing the Patient and Public Involvement and Engagement undertaken that describes the

acceptability of using identifiable data without consent, including the number of participants.

3. Provide a report, at the first annual review, of the ongoing activities of the parent advisory group.

4. Favourable opinion from a Research Ethics Committee (**Confirmed 28 September 2020**).

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 **Confirmed:**
    - **University of Leicester - College of Life Sciences (EE133832-CMBSP**),
    - **Chelsea & Westminster Hospital NHS Foundation Trust (RQM)**,
    - **University of Leeds -SEED (8E218-SEED)** and
    - **NHS Digital (X26) –**Equivalent to DSPT) **have a confirmed 'Standards Met' grade on DSPT submission 2018/19 (Confirmed by check of DSPT tracker 22 September 2020)**
    - Security assurances for **NHS Wales Informatics Service (NWIS)** have also been provided in the form of a CPiP out-turn report dated 15th June 2020.

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 **29 September 2021** 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 application form]		24 August 2020
Covering letter on headed paper [CAG cover letter]		06 August 2020
Data Protection Registration [University of Leicester DPA]		
Data Protection Registration [Chelsea & Westminster DPA]		
Data Protection Registration [Leeds DPA]		
GP/consultant information sheets or letters [Information letter for neonatal units]	1.0	05 August 2020
GP/consultant information sheets or letters [Information letter for PICU]	1.0	05 August 2020
Patient Information Materials [Privacy notice]	0.2	
Research protocol or project proposal [Protocol]	1.0	05 August 2020
283808_SL05_Favourable_opinion_at_first_review_28.09.2020		28 September 2020

Membership of the Committee

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

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

Caroline Watchurst
Confidentiality Advisor
On behalf of Health Research Authority

Email: cag@hra.nhs.uk

Enclosures:	*List of members who considered application* *Standard conditions of approval*
Copy to:	*Cambridgeeast.rec@hra.nhs.uk*

Confidentiality Advisory Group precedent set meeting attendance
11 September 2020

Members present:

Name	
Dr Patrick Coyle	CAG vice-chair
Mr Andrew Melville	CAG member
Mr David Evans	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Caroline Watchurst	HRA Confidentiality Advisor

Health Research Authority

Standard conditions of support

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

The applicant and those processing the information 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.

6. Activities remain consistent 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 supported 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.