Health Research Authority
2 Redman Place
Stratford
London
E20 1JQ

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

01 March 2021

Ms Jessica Ellis
Royal College of Paediatrics and Child Health
5-11 Theobalds Road
London
WC1X 8SH

Dear Ms Ellis,

Application title: **National Neonatal Audit Programme (NNAP) data flow**
CAG reference: **21/CAG/0007**

Thank you for submitting a **non-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 Secretary of State for Health and Social Care on whether application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 21 January 2021.

This outcome should be read in conjunction with the provisional support letter dated 03 February 2021.

Secretary of State for Health and Social Care decision

The Secretary of State for Health and Social Care, 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 contained in the BadgerNet system, for Clevermed Ltd to extract confidential patient information in a

dataset and further disclosure to the RCPCH Azure hosting infrastructure, is fully supported, subject to compliance with the standard 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 the Royal College of Paediatrics and Child Health (RCPCH) sets out the purpose of an audit programme, to assess whether babies admitted to neonatal units in England and Wales receive consistent high-quality care and to identify areas for service and quality improvement in relation to the delivery and outcomes of neonatal care.

The National Neonatal Audit Programme (NNAP) was established in 2006 and has, until now, been delivered by the RCPCH and is commissioned to do so by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The NNAP assesses whether babies admitted to neonatal units in England and Wales receive consistent high-quality care and identifies areas for service and quality improvement in relation to the delivery and outcomes of neonatal care as measured by adherence to a set of agreed professional guidelines and standards. Currently, for the 1 April 2017 to 31 March 2021 NNAP contract period, neonatal units use identical (BadgerNet) software to route clinical data via Clevermed Ltd into the National Neonatal Research Database (NNRD) dataset maintained at Imperial College by the Neonatal Data Analysis Unit (NDAU), (CAG reference: ECC 8-05(f) 2010). NNAP data is a sub-set of the wider NNRD and the NDAU processes NNAP data on behalf of the RCPCH to whom it provides quarterly and annual aggregated and anonymised reports.

The NNAP is not run or delivered by the National Neonatal Research Database (NNRD), as the Neonatal Data Analysis Unit (NDAU) within Imperial College is sub-contracted by the RCPCH to undertake data analysis for the NNAP and it does this by processing NNAP-related data within the NNRD using the legal basis given under CAG reference ECC 8-05(f)2010. The applicants are now seeking support under Regulation 5 of the COPI Regulations for the NNAP, so that NNAP will have its own support and will no longer come under ECC 8-05(f)2010.

Participating Neonatal units will input confidential patient information into the BadgerNet system on all babies admitted to all NHS neonatal units in England and Wales associated with a delivery unit, including special care units (SCUs), local neonatal units (LNUs) and neonatal intensive care units (NICUs). Data entered into BadgerNet is stored on servers within the Clevermed Microsoft Azure environment, accessible only via the HSCN NHS Network. A dedicated NNAP SQL Server Database will be created by Clevermed within its Azure environment for the sole purpose of hosting the national NNAP dataset extracted from the live BadgerNet system. Data for each neonatal care episode will be added to the dedicated NNAP SQL Server Database thirty days after the date of the baby's discharge from neonatal care. After this date any changes by users to that raw BadgerNet record will be synchronised to the dedicated NNAP database so that it always reflects the current raw BadgerNet care record. The NNAP Database within the Clevermed Azure environment can then be synchronised to a "mirror" instance of a NNAP SQL Server Database located on an entirely separate RCPCH Azure hosting infrastructure. Appropriately trained and approved RCPCH-based NNAP project staff will

be able to work with data within the NNAP database within the RCPCH Azure environment only and produce monthly, quarterly or whole-year analysis and reporting. A pseudonymised version of the NNAP data will be created within the RCPCH Azure environment and it is this pseudonymised version of the data that the NNAP project team will work with. The applicant confirmed that confidential patient information is put into the BadgerNet system by participating trusts as part of routine care and input into BadgerNet is outside the scope of the s251 support sought.

A recommendation for class 1, 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	The following inclusion criteria apply to all NNAP measures: • Babies who were admitted for neonatal care • Babies who had care provided by an NNAP-registered NHS neonatal unit • Babies whose parents or carers have not opted them out of secondary use of their data
Data sources	1. Confidential patient information entered by participating neonatal units into BadgerNet
Identifiers required for linkage purposes	1. NHS Number of baby 2. NHS number of mother
Identifiers required for analysis purposes	1. Date and time of baby's admission 2. Date of time of baby's discharge 3. Date and time of baby's birth 4. Baby's date of death 5. Mother's date of birth 6. Mother's ethnicity 7. Gender of baby 8. Postcode of mother's usual address

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. **Confirm that support is needed for the disclosure of confidential patient information from CleverMed to the NNAP sub-dataset, held within CleverMed, which will then be used to create the mirror dataset at RCPCH. The mirror dataset will then be used to create a pseudonymised dataset, held within RCPCH.**

The applicant confirmed that this was correct. Clevermed will create a NNAP Database, containing only data that has been entered into BadgerNet. A mirror of that NNAP database will then be used to create a pseudonymised NNAP database, which will be used by approved members of the NNAP project team for analysis. The CAG noted this information and raised no further queries.

2. **Clarify what will be done with the historical datasets, collected for the NNAP under the support for NNRD and held by the NDAU.**

The applicant explained that the RCPCH will request copies of the anonymised historical NNAP datasets which were processed by the NDAU for the NNAP on behalf of RCPCH. HQIP will remain as the data controller for NNAP data and the applicants have informed the NDAU staff that they will need to liaise with the CAG in relation to whether their support under Regulation 5 needs to be amended. The CAG noted this information and raised no further queries.

3. **Further details on the pseudonymisation process is required;**

    a. **Clarify whether staff from CleverMed or staff from RCPCH will access the identifiable mirror dataset in order to remove identifiers to create the pseudonymised dataset.**

The applicant clarified that only approved RCPCH staff will access the identifiable mirror NNAP dataset in order to remove identifiers to create the pseudonymised dataset.

    b. **If the pseudonymisation process is carried out by RCPCH staff, explain if it is possible for CleverMed staff to undertake this process instead. If it is not possible for CleverMed staff to undertake the process, provide an explanation on why this cannot be done.**

The applicant explained that RCPCH needed to undertake the pseudonymisation process as they need to be able to check for duplicate entries and update episodic tables before starting to analyse and work with the NNAP data.

    c. **If the pseudonymisation process will be undertaken by RCPCH staff, the provide details on what will be with the identifiers removed. The application advised that the identifiers would be retained for one year to check for duplicate records. Please confirm if this is correct.**

The applicant confirmed that the identifiers removed by RCPCH staff were the NHS numbers of baby and mother, mother's postcode, the dates of birth for mother and baby, and baby admission and discharge dates. The applicant also confirmed that the episodic data for each baby is compared to find the last known episode, and the last known neonatal discharge. If these details indicate the end of neonatal care, then the baby is assigned a "FinalYear" and "FinalQuarter" to indicate discharge from neonatal care. If the contract for the RCPCH to deliver the NNAP were to be extended beyond 31 March 2022 then an application would be made to the CAG to retain identifiers for the period of any such new contract to allow for continued longitudinal analysis, including checking for any historical inaccuracies in the data.

The CAG noted the above clarifications and raised no further queries.

4. **The following changes to the patient notification and dissent mechanism were requested;**

a. **Written materials, such as a poster, need to be created and provided to the CAG for review.**
b. **Details on the NNAP, including the processing of confidential patient information required for the purpose of the audit and how parents/carers can dissent to the inclusion of their child's data, need to be made available online.**

The applicant provided a draft of an updated NNAP Privacy Notice poster, to be displayed in neonatal units and on the NNAP information governance web page. The Privacy Notice would also be displayed on the NNAP website alongside a copy of the outcome letter from the CAG. The applicant also provided an example of a neonatal unit specific results poster. These are produced by the NNAP team each year. They show how a particular unit performed against the annual report key findings results at a national level. These posters also include a second poster page which units can populate with details of actions that have undertaken/are undertaking in response to their annual report results.

The CAG asked that the poster was revised to include further details on how patients can opt-out. A revised poster was returned, which was reviewed and accepted by the CAG.

c. **Further details on how the "Your baby's care" booklet will be disseminated need to be provided.**

The applicant advised that an initial batch of hard copies of the yearly update to 'Your Baby's Care' are sent to the registered NNAP clinical lead at each participating neonatal unit. Further copies can be provided on request by the project team. The booklet is also made available on the NNAP website. These are provided in an information pack which also includes a copy of their specific NNAP annual report key findings report poster. Neonatal units are asked to make copies of the 'Your Baby's Care' booklet available for parents and families to read alongside their unit-specific NNAP results posters. Further signposting of the NNAP privacy notice and Rights to dissent/object etc. will be included in the 2021 update of Your Baby's Care.

The CAG noted this information and raised no further queries.

5. **Further information on patient and public involvement needs to be provided:**

    a. **Please provide letters of support from BLISS and the parent representative, evidencing that they are supportive of the project.**

    b. **Please also confirm whether the processing of confidential patient information as required in this application has been specifically discussed during patient and public involvement, and provide feedback from these discussions.**

The applicant provided a letter of support from one of the parent representatives on the NNAP Methodology & Dataset Group and Project Board and a letter of support from BLISS. The CAG noted this 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 Secretary of State for

Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. 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: Royal College of Paediatrics and Child Health (by check of the NHS Digital DSPT tracker on 26 January 2021) has a confirmed 'Standards Met' grade on DSPT 2019/20)**
    - **Confirmed: CleverMed Ltd (by check of the NHS Digital DSPT tracker on 19 February 2021) has a confirmed 'Standards Met' grade on DSPT 2019/20)**

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 **01 March 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 are as follows.

Document	*Version*	*Date*
CAG application from (signed/authorised) [CAG Application form]		
Confidentiality policy [Data Protection and Confidentiality Policy]		
Other [21CAG0007_RCPCH SIRO letter of support]		
Other [NNAP 2021_2022 Data Flow Diagram]		
Other [Guide to the NNAP 2020 audit measures]		
Other [NNAP Privacy Notice_2020]		
Other [Checklist when handling personal or sensitive data]		
Other [Good handling practice remote working policy]		

Patient Information Materials [NNAP Your Baby's Care Booklet 2020]		
Written recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [21_CAG_0007 HQIP Letter of Support]		
Bliss letter of support for NNAP data flow		
NNAP Poster_BRADFORD ROYAL INFIRMARY_Page1		
Response to CAG re 21CAG0007 application 100221		10 February 2021
NNAP Parent Rep letter of Support_CAG_A Buck		
NNAP unit posters updated		
Bliss letter of support for NNAP data flow		
NNAP-Poster-2		
NNAP Parent Rep letter of Support_CAG_A Buck		
Response to CAG re 21CAG0007 application 100221		10 February 2021

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

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

Confidentiality Advisory Group meeting attendance
21 January 2021

Members present:

Name	
Dr Tony Calland MBE	CAG Chair
Mr David Evans	CAG member
Dr Liliane Field	CAG member
Mr. Myer Glickman	CAG member
Mr Tony Kane	CAG member
Professor Jennifer Kurinczuk	CAG member
Mr Andrew Melville	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair

Also in attendance:

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

Health Research Authority

Standard conditions of support

Support to process the specified confidential patient information without consent, given by the Secretary of State for Health and Social Care, 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 relevant 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.