



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.

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 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**

**a.**

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 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 m 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





**Confidentiality Advisory Group meeting attendance  
21 January 2021**

**Members present:**

<i>Name</i>	
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

## **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 amendmen