Health Research Authority

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17 February 2020

Miss Helen Sisson
Faculty of Health Sciences
University of Hull
Cottingham Rd, Hull
HU67RX

Dear Miss Sisson

Application title:	**Vaccination timeliness in preterm infants**
CAG reference:	**19/CAG/0197**
IRAS project ID:	**209347**
REC reference:	**19/EM/0351**

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 07 November 2019.

This outcome should be read in conjunction with the provisional outcome letter dated 22 November 2019.

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 from the Maternity Services Data Set to Information Services at Hull University Teaching Hospitals NHS Trust, and to allow further disclosure to Child Health Information Services and the National Neonatal Research Database for further data linkage and the return of an identifiable dataset to Information Services at Hull University Teaching Hospitals NHS Trust, 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 University of Hull set out the purpose of medical research that seeks to investigate the timeliness of primary vaccinations given to preterm infants.

All infants born in England are invited to be vaccinated according to an established schedule, however some evidence suggests that preterm infants (infants born at 37 weeks gestation or less) are not being vaccinated in a timely manner. This is a population particularly at risk of infection, and the applicant seeks to understand whether vaccinations are delayed and the reasons why this might be. The applicant has already undertaken and published a literature review, in which 14 studies were identified as demonstrating that preterm infants did experience delays in receiving vaccinations. Additionally, infants with the lowest gestational ages and the lowest birth weights experienced the greatest delays. The last UK study into this was undertaken in 2000 and the vaccination schedule has changed considerably since then.

The applicant will analyse existing data, routinely collated via established databases. The datasets used are the Maternity Services Data Set (MSDS), Child Health Information Service (CHIS), to access vaccination details for full term and preterm infants, and the National Neonatal Research Database (NNRD), for details on preterm infants. Data for infants due their primary vaccinations between 01 January 2018 and 30 June 2018 in the Humber Coast and Vale Local Maternity System will be requested from the corresponding MSDS and sent to Information Services at Hull University Teaching Hospitals NHS Trust. Information Services will then send the NHS numbers of identified patients to CHIS, to link with the infant's vaccination status, and to corresponding preterm data held in the NNRD. The NNRD operates with support under Section 251 and its Regulations under reference ECC 8-05(f)/2010. The CHIS and MSDS databases operate under directions from NHS England, with The Health and Social Care Act 2012, section 254, section 259(1), section 259(5) as the legal basis for processing. Support under Section 251 was therefore requested for data from the three databases to be linked in the trial dataset. The full dataset will then be anonymised before it is sent to the applicant for analysis.

A recommendation for class 1, 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	All infants born between 06 November 2017 and 05 May 2018 within the region covered by the Humber Coast and Vale Local Maternity System who are due their primary vaccinations (those offered at 8, 12 and 16 weeks of age) over a six-month period from January 1st 2018 to June 30th 2018. The total sample size is estimated as 6000 patients.
Data sources	1. Maternity Services data set (MSDS), provided by Northern Lincolnshire and Goole (NLAG) NHS Foundation Trust, York Teaching Hospital NHS Foundation Trust and Hull University Teaching Hospitals (HUTH) NHS Trust. 2. Child Health Information Service (CHIS), provided by Harrogate and District NHS Foundation Trust, Humber NHS Foundation Trust, NLAG NHS Foundation Trust and North East Lincolnshire Council 3. The National Neonatal Research Database (NNRD), managed by the Neonatal Data Analysis Unit (NDAU) at Imperial College London and Chelsea and Westminster NHS Foundation Trust.
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth (infants and mothers) 3. Date of death 4. Gender 5. Ethnicity
Identifiers required for analysis purposes	1. Date of birth (infants and mothers) 2. Date of death 3. Neonatal Unit Location 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice

The applicant's response to the provisionally supported outcome was considered by a sub-committee of the CAG.

1. **Justification for each of the identifiers requested for both infants and parents needs to be provided.**

The applicant explained that the infant's NHS number and date of birth were the only common identifiers required to link between the databases. The NHS number is unique to each infant, and the date of birth is required as a 'second check' that the correct data are linked. No identifiers would be used to link any parental data.

The dates of birth for the infants and dates of vaccinations are required to determine the primary and secondary outcome measures of the study which are to establish if a delay exists and if so, what the size of the delay looks like.

All other data would be used in the analysis to determine if there are any factors associated with timeliness.

The Group reviewed this information and queried whether it was necessary to retain the date of birth for parents after analysis, or if this could be replaced by age.

2. **Provide a specific date by which the confidential patient information used to facilitate linkage will be either pseudonymised or destroyed.**

The applicant advised that the Information Services at HUTH will undertake the data linkage and anonymization. Patient identifiable information will be kept by HUTH for 6 months from receipt to allow for data linkage and pseudonymisation. As HUTH will not receive all data on one occasion and will be waiting for data from a number of organisations, it is estimated that at the latest date at which data pseudonymisation will occur is 30th September 2020. The CAG reviewed this information and was satisfied that the query had been addressed.

3. **A study specific notification mechanism is to be created and placed on the websites for the University of Hull and participating Trusts. Provide a copy of this text for review.**

The applicant advised that they had looked at the information about current research projects on NHS Trust sites involved in the study and noted that the amount of information each Trust published varied. The applicant provided the text they would give to participating Trusts. This was reviewed by the CAG who was satisfied with the contents.

4. **Patient and public involvement is to be undertaken to test the acceptability of using confidential patient information without consent for the study purposes. Feedback provided to the CAG around the format of the activity, an overview of the individuals involved, and the views expressed.**

The applicant advised that the parents of infants who had already received 1-2 doses of the primary vaccinations were consulted about this project at an existing local group organised by Humber NHS Foundation Trust. The rationale for the study and a brief overview of the methods were discussed; in particular, parents were asked what they thought about the use of personal data without consent. Eight mothers were consulted and the feedback about the rationale for the study and its methods was entirely positive. The Group reviewed this information and was satisfied that the queries had been addressed.

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 standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from REC **Confirmed 04 December 2019.**

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. **Due to the number of sites processing under the application scope, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to accessing confidential patient information with support under the Regulations. This would need to be established at the following sites:**

- **Northern Lincolnshire and Goole (NLAG) NHS Foundation Trust**
- **York Teaching Hospital NHS Foundation Trust**
- **Hull University Teaching Hospitals (HUTH) NHS Trust.**
- **Harrogate and District NHS Foundation Trust**
- **Humber NHS Foundation Trust,**
- **North East Lincolnshire Council**
- **Chelsea and Westminster NHS Foundation Trust.**
- **Imperial College London.**

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 support is subject to submission of an annual review report to show 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.

Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support.

The annual review should be provided no later than **17 February 2021** and preferably 4 weeks before this date.

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.

For an annual review to be valid, there must be evidence that the relevant DSPT submission(s) are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the annual review submission, and submit evidence in the form of direct email from NHS Digital to evidence that 'standards met' grade are in place for all relevant DSPT submissions detailed in the conditions of support above.

Register of Approved Applications

All supported applications 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.

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. The amendment form can be found in the 'Guidance for CAG Applicants' section of the Health Research Authority website.

Support for any submitted amendment would not come into effect until a further 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 CAG application form 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.

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.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [CAG_Form_ReadyForSubmission]		19 September 2019
Covering letter on headed paper [HRA-CAG response to letter 29.11.19]		29 November 2019
Other [Sponsorship Confirmation]		19 July 2019
Other [8-05 (f) Neonatal database final outcome Jan 2012]		27 January 2012
Other [Data Management Plan v1 12-3-19]	1	12 March 2019
Other [Data transfer process v3 29-10-19]	3	29 October 2019
Other [Re NNRD query email]		11 August 2016
Other [Study approval NNRD email]		16 April 2019
REC favourable opinion letter and all correspondence [209347 19.EM.0351 Favourable Opinion at first review 04.12.2019]		04 December 2019
Research protocol or project proposal [Data transfer process v2 23-7-19]	2	23 July 2019
Research protocol or project proposal [Protocol v3 23-7-19]	3	23 July 2019
Written recommendation from Caldicott Guardian (or equivalent) of		16 September 2019

applicant's organisation [Agreement from Caldicott Guardian]		

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: HRA.CAG@nhs.net

Included:	List of members who considered application Standard conditions of support
Copy to:	nrescommittee.eastmidlands-nottingham2@nhs.net hra.approval@nhs.net

Confidentiality Advisory Group Sub Committee meeting held in correspondence

Members present:

Name	
Dr Tony Calland	CAG Chair
Mr David Evans	CAG member
Mr. Myer Glickman	CAG member
Mr Tony Kane	CAG member
Dr Simon Kolstoe	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor

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.