Health Research Authority

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31 March 2020

Professor Jennifer J Kurinczuk
University of Oxford
National Perinatal Epidemiology Unit
University of Oxford Old Road Campus
Headington, Oxford
OX3 7LF

Dear Professor Kurinczuk

Application title:	Neonatal Complications of Coronavirus Disease (COVID-19) Study
CAG reference:	20/CAG/0058
IRAS project ID:	282127
REC reference:	20/NE/0107

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.

Ordinarily, 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 by correspondence on 27 March 2020.

However, on 20 March 2020, the Secretary of State for Health and Social Care issued a notice under Regulation 3(4) of the Health Service Control of Patient Information Regulations 2002 (enclosed) This notice advises that action to be taken will require the processing and sharing of confidential patient information amongst health organisations and other bodies engaged in disease surveillance for the purposes of research, protecting public health, providing healthcare services to the public and monitoring and managing the Covid-19 outbreak and incidents of exposure. This notice applies until 20 September 2020 in the fist instance.

As such, it is the view of the HRA that CAG support is not required for your study. However, to support researchers and NHSX in maintaining a list of activities carried out under the terms of this notice, where so notified to HRA and/or NHSX, members of the Confidentiality Advisory Group have been asked to provide you with advice on your application.

Health Research Authority advice

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

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to determine the incidence of neonatal COVID-19, including hospital acquired infection, and the incidence of transmission from mother to baby during pregnancy, labour and birth.

Coronavirus is a new virus that has come from China, where it was first recognised as causing a new infection (COVID-19) in late 2019. Little information is available about how the virus affects mothers and new-born babies and it is not clear how best to care for mothers and babies affected. Little is also known about how babies become infected with Coronavirus and whether it transmits from mothers to their baby(s) while they are still pregnant, during labour and birth, or whether the infection occurs following birth. Understanding this will mean that better care can be given to mothers and babies and the best advice to pregnant women about the effects of Coronavirus on their baby.

Information about new-born babies who have Coronavirus or who are born to mothers who have Coronavirus. This information will be used to building understand of how babies get Coronavirus, what happens to babies when their mother has Coronavirus, the treatments that are effective in helping babies with Coronavirus to get better, and what happens to babies following treatment.

The British Paediatric Surveillance Unit (BPSU) will be used to carry out the study. Each week every doctor across the UK looking after new-born babies in hospital will be asked by the BPSU if they have looked after a new-born baby with Coronavirus or whose mother has Coronavirus. If they have, the clinicians will be sent a questionnaire to collect information about the baby and their mother. Wider linkages will also be made with the National Neonatal Research (NNRD), the Paediatric Intensive Care Audit Network (PICANet), and the national surveillance of maternal and perinatal deaths (MBRRACE-UK), alongside cross checks with the UKOSS maternal study and PHE, PHS and the similar systems of notification of infectious diseases in Wales and Northern Ireland, to ensure complete case ascertainment. Consent will not be sought from patients due to the urgent need to collect information on all affected baby's, therefore support under s251 is sought to process confidential patient information for the mothers and babies.

A recommendation for class 2,4,5 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	Any child in England and Wales that has a diagnosis of COVID-19, made on a sample taken prior to 29 days of age, who has received inpatient care for COVID-19. Any child in England and Wales whose mother had confirmed COVID-19, or suspected COVID-19 and the diagnosis was later confirmed, at the time of birth, and the baby was admitted for neonatal care. It cannot currently be estimated how many patients will be included in the cohort.
Data sources	1. Paediatricians within Trusts who report eligible patients through BPSU 2. The National Neonatal Research (NNRD) 3. The Paediatric Intensive Care Audit Network (PICANet) 4. The national surveillance of maternal and perinatal deaths (MBRRACE-UK) 5. The UKOSS maternal study 6. PHE 7. PHS
Identifiers required for linkage purposes	1. NHS Number 2. Date of Birth 3. Date of Death 4. Postcode – District Level 5. Ethnicity of baby
Identifiers required for analysis purposes	1. Date of Birth 2. Date of Death 3. Postcode – District Level 4. Gender 5. Ethnicity of baby

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the advice from 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 had a clear medical purpose and falls under the notice and instructions from Secretary of State mentioned above, requiring NHS and other organisations to process confidential patient information, strictly for the purposes set out in that notice.

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

It was not practicable to seek consent from individual patients due to the urgent need to collect information and the necessity that information about all affected babies was collected. Linkages needed to be made to further information to ensure that a complete picture of the impact of COVID-19 on all affected mothers and babies was carried out and to prevent de-duplication of cases. The CAG agreed that it was not feasible to seek consent.

- Use of anonymised/pseudonymised data

Confidential patient information was required to undertaken linkages to further information to ensure that a complete picture of the impact of COVID-19 on all affected mothers and babies was carried out and to prevent de-duplication of cases. The CAG agreed that this could not be done in any other way.

'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 applicant noted that parents could not opt-out of the notification being sent via BPSU, but could opt-out of the data collection. This can be done by letting their baby's doctor know or by contacting the study team by email, telephone or written contact. If the research team are notified that a parent wishes to remove their child's data, then any information already received will be deleted and will not be included in the study. The Group advised that the data for these patients should not be included in any data linkages. The applicants will retain the fact that there was an eligible baby, to ensure that the incidence estimates produced are as accurate as possible.

A poster, information leaflet and website text were provided with the application. The Group noted that the leaflet and poster did not contain the same contact details for the research team as those on the poster. Members asked that these were revised for consistency.

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 applicant acknowledged that the patient and public involvement carried out was limited due to the urgent nature of the application. The Policy Research Unit PPI co-leads reviewed the application and parent facing information. The MBRRACE-UK stakeholder group, an established group who represent relevant baby charities and service users, reviewed the poster and privacy notice. Feedback was supportive of the aims of the study and the processing of confidential patient information without consent.

Feedback was also sought from AIMS (for better births), Sands, the multiple birth foundation MBF, ICP support, Action against Pre-eclampsia APEC, Birthrights, the Birth Trauma Association, and Action against medical accident AvMA. Feedback was supportive and examples of the comments received were included in the application.

The comments received on the parent-facing materials were incorporated into the materials. Additional information was also added to the protocol, in line with the feedback received.

The Group commended the applicants on the patient and public information and engagement they had undertaken in such a short time.

Confidentiality Advisory Group advice conclusion

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

Specific advice

1. The poster, information leaflet and website text need to contain the same contact details for the research team.

2. Favourable opinion from a Research Ethics Committee will still be required

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed – Nuffield Department of Population Health, University of Oxford has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 01 November 2019).**

Annual Review

Please note that the CAG advises that on expiry of the Secretary of State's notice and instructions, it is likely that you will be required to submit an annual review report to show how you have taken the advice, and actions towards implementing it as well as any other, statutory, obligations. Subject to clarification from NHSX on how activities that commence under the terms of the notice should be managed on its expiry, it is also likely to be your responsibility to submit this report on the anniversary of your REC approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should be provided no later than **31 March 2021** and preferably 4 weeks before this date.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [20_CAG_Form_Submitted]		26 March 2020
Covering letter on headed paper [01_Signed sponsor letter PID14905 J Kurinczuk]		25 March 2020
Data Protection Registration [17_ICO registration University of Oxford]		
Other [03_BPSU_Data analysis plan - neonatal COVID19 25th March V1]	1	25 March 2020
Other [05_BPSU-COVID19 dataflow 25th March V1]	1	25 March 2020
Other [09_COVID-19 study privacy notice 25th March 2020 V1]	1	25 March 2020
Other [10_DHSC funder letter BPSU study 23.03.2020]		23 March 2020
Other [11_Bliss letter of support - COVID research 20_03_20]		20 March 2020
Other [12_Sands letter of support 17_03_2020 SUBMITTED]		20 March 2020
Other [16_UoO CT insurance 19 20]		
Patient Information Materials [04_Neonatal COVID19-BPSU questionnaire 25th March 2020 V1]	1	25 March 2020
Patient Information Materials [06_Parent information leaflet COVID-19 study 25th March 2020 V1]	1	25 March 2020
Patient Information Materials [07_BPSU COVID19 Poster V1 25th March 2020]	1	25 March 2020
Patient Information Materials [08_COVID-19 webpage text 25th March 2020 V1]	1	25 March 2020
Patient Information Materials [13_COVID-19 BPSU letter to accompany questionnaire 25th March V1]	1	25 March 2020
Patient Information Materials [14_COVID-19 BPSU reminder letter for notification follow up questionnaire 25th March 2020 V1]	1	25 March 2020
Patient Information Materials [15_COVID-19 BPSU thank you letter following completion of questionnaire 25th March V1]	1	25 March 2020
Research protocol or project proposal [02_COVID-19 neonatal study protocol NPEU 25th March 2020 v1]		25 March 2020
Written recommendation from Caldicott Guardian (or equivalent) of applicant's organisation	2	27 March 2020

Membership of the Committee

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

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 Health Research Authority

Email: cag@hra.nhs.uk

Enclosures: *List of members who considered application*
Standard conditions of approval

Copy to: newcastlenorthtyneside2.rec@hra.nhs.uk

Confidentiality Advisory Group meeting attendance, held by teleconference on 27 March 2020

Members present:

Name	
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Dr Rachel Knowles	CAG member
Mr Marc Taylor	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr Jonathan Fennelly-Barnwell	HRA Deputy Director
Ms Juliet Tizzard	HRA Director of Policy
Ms Catherine Adams	Approvals Manager