Professor Jennifer J Kurinczuk
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30 March 2020

Dear Professor Kurinczuk

**HRA and Health and Care Research Wales (HCRW) Approval Letter**

| | |
|---|---|
| **Study title:** | **Neonatal Complications of Coronavirus Disease (COVID-19) Study** |
| **IRAS project ID:** | **282127** |
| **REC reference:** | **20/NE/0107** |
| **Sponsor** | **University of Oxford** |

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

**How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?**
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

**How should I work with participating non-NHS organisations?**
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

**What are my notification responsibilities during the study?**

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

**Who should I contact for further information?**
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **282127**. Please quote this on all correspondence.

Yours sincerely

Catherine Adams

Approvals Manager
Email: approvals@hra.nhs.uk

*Copy to:* *CTRG*

## List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

| *Document* | *Version* | *Date* |
|---|---|---|
| Copies of advertisement materials for research participants [BPSU COVID19 Poster] | 2 | 30 March 2020 |
| Covering letter on headed paper [Invitation letter to doctor] | | 25 March 2020 |
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance letter] | | 01 August 2019 |
| HRA Schedule of Events | 1 | 30 March 2020 |
| IRAS Application Form [IRAS_Form_26032020] | | 26 March 2020 |
| IRAS Application Form XML file [IRAS_Form_26032020] | | 26 March 2020 |
| IRAS Checklist XML [Checklist_26032020] | | 26 March 2020 |
| Letter from funder [Funder letter] | | 23 March 2020 |
| Letter from sponsor [Sponsor letter] | | 25 March 2020 |
| Non-validated questionnaire [Data collection sheet] | V6 | 25 March 2020 |
| Organisation Information Document | 2 | 30 March 2020 |
| Other [Data analysis plan] | V1 | 25 March 2020 |
| Other [Data flow diagram] | V1 | 25 March 2020 |
| Other [Bliss letter of support] | V1 | 20 March 2020 |
| Other [Sands letter of support] | V1 | 17 March 2020 |
| Other [Doctor reminder letter] | V1 | 25 March 2020 |
| Other [Doctor thank you letter] | V1 | 25 March 2020 |
| Other [ICO registration] | V1 | 12 September 2019 |
| Other [Data flow diagram] | 1 | 30 March 2020 |
| Other [Privacy Notice] | 2 | 30 March 2020 |
| Other [Webpage text] | 2 | 30 March 2020 |
| Participant information sheet (PIS) [Parent Information Leaflet] | 2 | 30 March 2020 |
| Research protocol or project proposal [Study protocol ] | V1 | 25 March 2020 |
| Summary CV for Chief Investigator (CI) [CV CI] | | 25 March 2020 |
| HRA Schedule of Events | 1 | 30 March 2020 |
| Organisation Information Document | 2 | 30 March 2020 |

| IRAS project ID | 282127 |
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## Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

| Types of participating NHS organisation | Expectations related to confirmation of capacity and capability | Agreement to be used | Funding arrangements | Oversight expectations | HR Good Practice Resource Pack expectations |
|---|---|---|---|---|---|
| All sites will perform the same research activities therefore there is only one site type.<br>All NHS Trusts and Health Boards in the UK who have at least one paediatrician receiving the monthly BPSU Orange Cards surveillance are participating in surveillance. For the purposes of this study the surveillance | Organisations will not be required to formally confirm capacity and capability, and research procedures may begin 35 days after provision of the local information pack, provided the following conditions are met.<br>• You have contacted participating NHS organisations (see below for details)<br>• HRA and HCRW Approval has been issued | An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used. | Department of Health and Social Care funded NIHR Policy Research Unit in Maternal and Neonatal Health and Care | The Chief Investigator will be responsible for all research activities performed at study sites | No access arrangements are expected for this study |

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| cards will be sent out weekly. | • The NHS organisation has not provided a reason as to why they cannot participate<br>• The NHS organisation has not requested additional time to confirm.<br><br>You may start the research prior to the above deadline if HRA and HCRW Approval has been issued and the site positively confirms that the research may proceed.<br><br>You should now provide the local information pack for your study to your participating NHS organisations. A current list of R&D contacts is accessible at the NHS | | | | |

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|---|---|---|---|---|---|
| | RD Forum website and these contacts MUST be used for this purpose. The password to access the R&D contact list is Redhouse1 | | | | |

**Other information to aid study set-up and delivery**

| *This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.* |
|---|
| All NHS Trusts and Health Boards in the UK who have at least one paediatrician receiving the monthly BPSU Orange Cards surveillance are participating in surveillance. For the purposes of this study the surveillance cards will be sent out weekly. |