

Oxford Tropical Research Ethics Committee

University of Oxford
Research Services, University Offices
Wellington Square, Oxford OX1 2JD
Tel. +44 (0)1865 (2)82106
E-mail: oxtrece@admin.ox.ac.uk



Professor Jose Villar
Nuffield Department of Women's & Reproductive Health
The Women's Centre
Level 3, John Radcliffe Hospital
Oxford
OX3 9DU

16 April 2020

Dear Professor Villar,

Full Title of Study: Effects of COVID-19 in pregnancy on maternal, fetal and newborn outcomes in the INTERGROWTH-21st global network

OxTREC Reference: 526-20

Thank you for your email of the 16 April 2020, and for your minimal risk application form.

I am pleased to confirm that approval has now been granted for this study. This is valid for the first five years and is subject to receiving the local ethical approval (if this approval has not yet been received).

The documents approved for this study are as follows:

Documents:	Version:	Date:
Minimal risk application form		
PIS	V1.0	15/04/20
ICF	V1.0	15/04/20

Any subsequent changes to the application must be submitted to the Committee as an Amendment. This should include a letter to give the reasons for the proposed modifications and all revised documents with changes tracked.

Please ensure that you submit a completed Annual Report form on every anniversary of this approval and a final End of Study Report. The relevant forms can be found on the OxTREC website: <https://researchsupport.admin.ox.ac.uk/governance/ethics/apply/oxtrece>.

Finally, please note the following **important information**:

Data safety—all studies

It is the responsibility of the PI to ensure that all data collected during the course of the study is stored and transferred safely and securely. Further guidance and advice is available from the [Research Data Team](#).

Studies that will involve storing human tissue samples in Oxford

As you are planning to import the samples into England, you will need to make arrangements

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before the samples are transferred to store them under the governance of a Human Tissue Authority (HTA) licence. It is a legal requirement that any tissue or fluid made up of or containing human cells to be used for the purpose of research is stored on premises licensed by the HTA unless covered by an exemption. OxTREC approval is not a recognised exemption. Further information may be found on the University's human tissue governance web pages: <https://researchsupport.admin.ox.ac.uk/governance/human-tissue>.

Yours sincerely

A handwritten signature in black ink that reads 'Rebecca Bryant'.

Dr Rebecca Bryant
Research Ethics Manager, OxTREC