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20th November 2024

Professor Julia Hippisley-Cox
University of Oxford

Dear Professor Hippisley-Cox

Reference	OX317
Title	Safety of Medicines in Pregnancy
Chief Investigator(s)	Prof Julia Hippisley-Cox
Date application submitted	25.09.2024
Date application reviewed	04.11.2024
Decision	Approve

Thank you for submitting your amendment application to QResearch.

Scientific Opinion

The members of the committee taking part in the review gave a favourable scientific opinion of the application on the basis of the application form and lay summary submitted to QResearch. The committee is satisfied that the research is appropriately designed in relation to its objectives and is likely to add something useful to existing knowledge in accordance with section 4.1.2 of the ethical conditions for QResearch.

<https://www.qresearch.org/media/1155/257790-18em0400-qresearch-conditions-of-ethical-approval-27122018.pdf>

QResearch is a Research Ethics Approved Research Database and therefore this also constitutes research ethics approval. Please quote REC reference (23/EM/0166) in any publication arising from this work.

Data Access

Subject to funding and relevant Data Sharing Agreements, the dataset requested will be provided to you.

Approved documents

The documents reviewed were

Document	version	Date
Application form		25.09.2024
Lay Summary		25.09.2024
Data Specification		25.09.2024

The Nuffield Department of Primary Care Health Sciences is part of the NIHR School for

Primary Care Research. Head of Department: Professor Richard Hobbs FRCGP FRCP FESC FMedSci



Response to last review	30.10.2024
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Reviewing Members of the Committee

The members of the scientific committee who took part in the review are listed on the attached sheet.

Annual Review and research outputs

We will contact you annually for an update on progress with your research.

Amendments and changes in responsibility

Any changes to the protocol or responsibility of the applicants for the conduct of the research should be notified to QResearch@phc.ox.ac.uk



Dr Paula Dhiman
Chair of QResearch Scientific Committee

Enclosures:

*List of names and professions of members who took part in the review
Completed peer review forms*

Copy to: Prof Julia Hippisley-Cox, Chief Investigator of QResearch.

Reviewing Members of the Committee

Name	Profession
Dr Paula Dhiman	Chair of the QResearch Scientific Committee
Dr Kate Best	Medical Statistician
Koen Pouwels	Statistician and Associate Professor
Ms Rebecca Harmston	Lay member
Dr Hui Guo	Senior Lecturer in Biostatistics
Mr Andrew Snelling	Data Scientist
Mrs Claire Meadows	Secretary