

23rd April 2020

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Dear Dr Patel,

RE: ExtraCorporeal Membrane Oxygenation for 2019 novel Coronavirus Acute Respiratory Disease (ECMOCARD Study)

Thank you for your enquiry seeking clarity on whether your project should be classified as research and whether it requires ethical review by an NHS Research Ethics Committee (REC).

You provided the following information:

- ECMOCARD Protocol v1.2.5, 23rd February 2020
- ECMOCARD EOT Data Entry v1.0 24Feb2020
- ECMOCARD DATA DICTIONARY v1.2.5 FINAL
- ECMOCARD CRF v1.2.5

Based on the information you have provided, our decision is that the project is **not considered to be research and does not require review by an NHS Research Ethics Committee.**

This decision is based on consideration that it is designed to investigate the health issues in a population in order to improve population health and to investigate an outbreak or incident to help in disease control and prevention

This decision is in line with:

- [Governance Arrangements for Research Ethics Committees](#)

- [UK Policy Framework for Health and Social Care Research](#)
- The National Research Ethics Service (NRES) *Defining Research* table (linked to from the first page of the '[Is it research?](#)' Decision Tool)
- Algorithm *Does my project require review by an NHS Research Ethics Committee?* (linked in the footer of the '[Do I need NHS REC review?](#)' Decision Tool)

This decision should not be interpreted as giving a form of ethical approval or endorsement to your project on behalf of the HRA. However, it may be provided to a journal or other body as evidence if required.

Please note that this decision was based on the information provided to us as listed above. If any changes are made to information you provided, this may alter the decision.

You should also be aware that:

- This response only covers whether your project is classified as research and whether it requires review by an NHS REC. You are strongly advised to consider other approvals that may be required for your project.
- All types of study involving human participants should be conducted in accordance with basic ethical principles, such as informed consent and respect for the confidentiality of participants. Also, in processing identifiable data there are legal requirements under the Data Protection Act. When undertaking an audit or service/therapy evaluation, the investigator and their team are responsible for considering the ethics of their project with advice from within their organisation.

Yours sincerely



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