

East of England - Cambridge Central Research Ethics Committee

Royal Standard Place
Nottingham
NG1 6FS

Tel: 0207 104 8388

02 June 2020

Dr Frances Hall
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Box 194
CB2 0QQ

Dear Dr Hall

Study title: Multiarm Therapeutic study in pre-ICU patients admitted with COVID-19 - Repurposed Drugs (TACTIC-R)
REC reference: 20/EE/0135
Protocol number: TACTIC-R
EudraCT number: 2020-001354-22
Amendment number: Substantial Amendment 1
Amendment date: 22/05/2020
IRAS project ID: 282213

The above amendment was reviewed the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee did not raise any ethical issues.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Cover Letter		22 May 2020
IRAS Application Form		20 May 2020
Other [Sponsor authorisation email]		22 May 2020

Other [MHRA Approval]		27 May 2020
Participant information and informed consent form [TACTIC-R_Endothelial cell collection PIS ICF]	V1.0	20 May 2020
Participant information and informed consent form [TACTIC-R_Short PISICF]	V1.0	20 May 2020
Research protocol or project proposal [TACTIC-R_Protocol - Clean]	V2.0	20 May 2020
Research protocol or project proposal [TACTIC-R_Protocol - Tracked Changes]	V2.0	20 May 2020

Membership of the Committee

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

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities— see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

20/EE/0135:	Please quote this number on all correspondence
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Yours sincerely



On Behalf Of
Miss Stephanie Ellis
Chair

E-mail: cambridgecentral.rec@hra.nhs.uk

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Attendance at Sub-Committee of the REC meeting on 28 May 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Miss Stephanie Ellis	Former Civil Servant	Yes	Chair
Revd Dr Derek Fraser	Chaplain	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Taimoor Hassan	Approvals Administrator