

East of England - Essex Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

29 July 2019

Dear Tony Whitehouse,

Study title: STRESS-L: STudy into the REversal of Septic Shock with Landiolol (Beta Blockade)
REC reference: 17/EE/0368
Protocol number: STRESS-L
EudraCT number: 2017-001785-14
Amendment number: Notice of Substantial Amendment 10
Amendment date: 03 July 2019
IRAS project ID: 213669

The above amendment was reviewed on 15 July 2019 by 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.

Discussion

No ethical issues raised.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Cover Letter]		08 July 2019
Notice of Substantial Amendment (CTIMP)	Notice of Substantial Amendment 10	03 July 2019
Other [Protocol Summary of Changes]		02 April 2019
Research protocol or project proposal [Protocol, Tracked]	V4.0, Tracked	02 April 2019

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.

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/>

17/EE/0368:	Please quote this number on all correspondence
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Yours sincerely,



P.P
Dr Gerry Kamstra
Chair

E-mail: NRESCCommittee.EastofEngland-Essex@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Ms Emma Skilton*

East of England - Essex Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 15 July 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>
Dr Gerry Kamstra	Retired Solicitor	Yes
Dr Nkiruka Umaru	Pharmacist	Yes

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Katie Arnold	Approvals Administrator