



Health Research Authority

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.

18 December 2018

Miss Nafisa Boota
Warwick Clinical Trials Unit
University of Warwick, Gibbet Hill Campus
Coventry
CV4 7AL

Dear Miss Boota

Study title:	STRESS-L: SStudy 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:	7
Amendment date:	30 November 2018
IRAS project ID:	213669

The above amendment was reviewed on 03 December 2018 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: There were no ethical concerns raised.



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Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [STRESS-L Relatives poster v1.0 29 October 2018.docx]	1	29 October 2018
Covering letter on headed paper [REC Cover Letter_30 November 2018.pdf]		30 November 2018
Notice of Substantial Amendment (CTIMP) [AmendmentFormMHRAEudract_ReadyForSubmission.pdf]	7	30 November 2018
Participant consent form [STRESS-L Consent Form V3.0 18 October 2018.docx]	3	18 October 2018
Participant consent form [STRESS-L Legal Rep CF V3.0 18 October 2018.docx]	3	18 October 2018
Participant information sheet (PIS) [STRESS-L Legal Rep Info Sheet V3.0 18 October 2018.docx]	3	18 October 2018
Participant information sheet (PIS) [STRESS-L Patient Information Sheet V3.0 18 October 2018.docx]	3	18 October 2018
Participant information sheet (PIS) [STRESS-L SHORT PIS V3.0 18 October 2018.docx]	3	18 October 2018
Research protocol or project proposal [STRESS-L Protocol v3.0 18 Oct 2018.docx]	3	18 October 2018
Research protocol or project proposal [Table of protocol changes v3.0 18 October 2018.pdf]	3	18 October 2018

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.

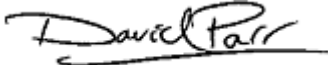
We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>



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

PP 

Dr Gerry Kamstra
Chair

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

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

*Copy to: Dr Chris Counsell, University Hospitals NHS Foundation Trust
Tony Whitehouse, Queen Elizabeth Hospital Birmingham NHS
Foundation Trust*

East of England - Essex Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 03 December 2018

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Shahira Amr	Pharmacist	Yes	
Dr Gerry Kamstra	Retired Solicitor	Yes	
David Parr	REC Assistant	Yes	