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.

15 April 2020

Ms Emma Skilton
Warwick Clinical Trials Unit
University of Warwick, Gibbet Hill Campus
Coventry
CV4 7AL

Dear Ms Skilton

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:	**Substantial Amendment 14**
Amendment date:	**19 February 2020**
IRAS project ID:	**213669**

The above amendment was reviewed 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.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Annex 2: Notification of Amendment	Substantial Amendment 14	19 February 2020

Covering letter on headed paper		20 February 2020
Other [Legal Rep Info Sheet Clean]	4.0	24 January 2020
Other [Legal Rep Info Sheet Tracked]	4.0	24 January 2020
Other		20 February 2020
Participant information sheet (PIS) [clean]	4.0	24 January 2020
Participant information sheet (PIS) [tracked]	4.0	24 January 2020
Research protocol or project proposal [clean]	5.0	17 December 2019
Research protocol or project proposal [tracked]	5.0	17 December 2019
Research protocol or project proposal [version log]	5.0	

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**

Yours sincerely

pp. V. Sutton

Dr Niki Bannister
Chair

E-mail: Essex.REC@hra.nhs.uk

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

Copy to: *Dr 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 01 April 2020

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Niki Bannister (Chair)	Retired Hospital Doctor	Yes	
Dr Gerry Kamstra	Retired Solicitor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Vic Strutt	Approvals Officer