

02 August 2018

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

Dear Miss Boota,

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:	SA_05
Amendment date:	31 July 2018
IRAS project ID:	213669

Thank you for submitting the above amendment, which was received on 02 August 2018. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		31 July 2018
Notice of Substantial Amendment (CTIMP)	SA_05	31 July 2018
Other [CSM Europe - Manufacturing Import Authorization]		01 December 2016
Other [GMP certificate CSM Germany April 2017]		04 April 2017
Other [LDLL300_CoC_CoA_Batch 1804_RJ]		20 April 2018
Research protocol or project proposal [STRESS-L Protocol]	2.0	31 July 2018

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

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

17/EE/0368:

Please quote this number on all correspondence

Yours sincerely,



Katharine Loven
REC Assistant

Email: NRESCommittee.EastofEngland-Essex@nhs.net

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