

20 February 2020

Dear Members of the NRES Committee East of England – Essex,

Study title: STRESS-L - Study into the Reversal of Septic Shock with Landiolol (Beta Blockade)

REC reference: 17/EE/0368

Amendment number: SA_14

Amendment date: 04 February 2020

IRAS Project ID: 213669

RE: Substantial Amendment - CTIMP

Please find attached a signed IRAS substantial amendment form, table of protocol changes alongside the following amended documents for the STRESS-L trial;

Document	Version	Date
STRESS-L Protocol	5.0	17 December 2019
STRESS-L Patient Information Sheet	4.0	24 January 2020
STRESS-L Legal Representative Information Sheet	4.0	24 January 2020

Please see the table of protocol changes which includes the old and new/additional wording for Protocol v5.0, 17 December 2019. The inclusion and exclusion criteria has been updated to clarify the patient population required alongside other amendments regarding safety reporting and definition of End of Noadrenaline Treatment Visit timepoint. Please refer to the signed IRAS substantial amendment form for further information regarding the justification for these key changes.

The Patient Information Sheet and Legal Representative Information sheet have been updated with a minor clarification regarding the method use to extract blood from the patient as part of their standard clinical care.

This amendment also includes the addition of the following new NHS site:

	Principal Investigator	NHS Organisation
1	Dr Atul Garg	Walsall Healthcare NHS Trust, Moat Road, Walsall, WS2 9PS

I hope this is satisfactory. Please do not hesitate to contact me should you require further information.

Kind regards



Emma Skilton
Clinical Trial Manager