

Janis Best-Lane

Clinical Trial Manager

Room 5.03, 5th Floor, Medical School Building
Imperial College London, St Marys Campus

Norfolk Place, London W2 1PG

Tel: +44 (0)778 0600378

Email: j.best-lane@imperial.ac.uk

Email: septic@imperial.ac.uk

22nd December 2023

REC Reference: 23/LO/0339

IRAS Reference: 1005848

Dear HRA, REC and MHRA

SepTiC Trial Non-Substantial Amendment AM001

I am writing to you regarding the submission of a non-substantial amendment for the SepTiC Trial.

We would like to submit the following changes:-

1. Updated labels – providing more detail and format changes to the already approved labels- new labels included in the submission.

2. Consent forms for PerLR – typographical error we need to change from ‘England/Wales’ to ‘England/Wales/Northern Ireland’ – see tracked version attached

2a Telephone consent – after feedback from sites, due to this patient group (critical care) patients/families may not have access to email and so have requested a telephone form which allows sites to explain the study via telephone used in previous studies:- BLING III and REMAP-CAP.

2b Postal consent – similar to the point above, The REC for advice on this and they agreed we should submit this as an amendment. This will be used in circumstances where the patient is discharged before the site obtains written retrospective consent, the site will call the patient to explain the study and send the consent by post. Points 2a and 2b are linked here.

3. We will add another 7 NHS sites and PIs to the study, and change the PIs at 4 sites

4. Non-substantial changes to the IMPD

All information has been updated on the attached amendment tool

If you need any further information or documentation please let me know.

Janis Best-Lane
Clinical Trial Manager – SepTiC Trial