



Department of Paediatrics
University of Cambridge
Level 8 Addenbrooke's Hospital
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge CB2 0QQ

Dr Hilary Paniagua
REC Chair
West Midlands – Black Country REC
Health Research Authority
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

08 November 2021

Dear Dr Paniagua

Study title:	A pilot cluster randomised clinical trial of the use of selective gut decontamination in critically ill children (Paediatric Intensive Care and Infection Control)
REC reference:	20/WM/0061
IRAS number:	239324
Substantial amendment:	3

We wish to seek a substantial amendment for the above study. The purpose of this amendment is to update the protocol.

As we prepare to commence the SDD-enhanced infection control phase of the study, we would like to offer greater clarity on the mode of administration for the SDD suspension in the children participating in the SDD-enhanced infection control arm of the study.

Enteral drugs and feed can be administered by nasogastric, nasojejunal and percutaneous gastrostomy routes. In our protocol we have stated administration would be by nasogastric route but the constituent agents of the SDD are suitable for enteral administration by the other routes used. The tubes are of the same material, and we have added in a minimum diameter to be more precise on how it is given (flushing the tube before and after with sterile water).

This amendment brings us into line with the protocol followed by the adult SUDDICU study which utilises the same formulation of suspension and has been approved by both the sponsor pharmacist (Wendy Gooding, Cambridge University Hospitals NHS Foundation Trust) and trial pharmacist (Robert Shulman, UCLH).

We would be grateful if you could consider an expedited review as we are due to start the intervention as of the 29th November 2021. This study is on the managed recover programme with NIHR so we are keen to optimise enrolment by ensuring we do not

inadvertently not administer enteral SDD suspension to children with a tube that is nasojunal or percutaneous gastrostomy.

Please find enclosed the following supporting documents:

- *PICnIC Protocol V4.0, 08 November 2021_tracked changes*
- *PICnIC Protocol V4.0, 08 November 2021*

Kind regards

A handwritten signature in black ink, appearing to be 'Dr Nazima Pathan', with a stylized flourish at the end.

Dr Nazima Pathan FRCPCH PhD
Associate Professor in Paediatric Intensive Care