

Re issue 17th October 2018 – to correct date



West Midlands - Black Country Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

06 June 2018

Dr Kevin Goss
Consultant Neonatologist and Honorary Senior Lecturer
Leeds Teaching Hospitals NHS Trust
Leeds Neonatal Service
Leeds Childrens Hospital
Gt George Street, Leeds
LS1 3EX

Dear Dr Goss,

Study title:	OPTI-SURF: Optimal surfactant delivery for preterm babies with respiratory distress syndrome. The effect of surfactant dose on outcomes in preterm infants with Respiratory Distress Syndrome
REC reference:	18/WM/0132
IRAS project ID:	237111

Thank you for your letter of 23 May 2018. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 01 May 2018

Documents received

The documents received were as follows:

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<i>Document</i>	<i>Version</i>	<i>Date</i>
Response to Request for Further Information		23 May 2018

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [OPTI-SURF POSTER]	v1.1	05 April 2018
Covering letter on headed paper [Covering letter]		29 March 2018
GP/consultant information sheets or letters [Introduction Letter]	v1.1	18 March 2018
GP/consultant information sheets or letters [Additional Letter]	v1.1	18 March 2018
IRAS Application Form [IRAS_Form_13042018]		13 April 2018
Participant consent form [OPT-OUT FORM]	v1.1	18 March 2018
Participant information sheet (PIS) [OPTI-SURF ADMISSION LEAFLET]	v1.2	05 April 2018
Research protocol or project proposal [Protocol]	v2.1	13 February 2018
Response to Request for Further Information		23 May 2018
Summary CV for Chief Investigator (CI) [Dr Kevin Colin William GOSS]		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study recruitment: Algorithm for neonatal units]	v1.1	18 March 2018

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

18/WM/0132	Please quote this number on all correspondence
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Yours sincerely,



Rebecca Morledge
REC Manager

E-mail: nrescommittee.westmidlands-blackcountry@nhs.net

Copy to: *Dr Rachel Malone*
Donna Johnstone, Leeds Teaching Hospitals NHS Trust