

**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,

<b>Study title:</b>	<b>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</b>
<b>REC reference:</b>	<b>18/WM/0132</b>
<b>IRAS project ID:</b>	<b>237111</b>

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:

<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	01 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.

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



**Rebecca Morledge**  
**REC Manager**

E-mail: [nrescommittee.westmidlands-blackcountry@nhs.net](mailto:nrescommittee.westmidlands-blackcountry@nhs.net)

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