

OPTI-SURF Study Team

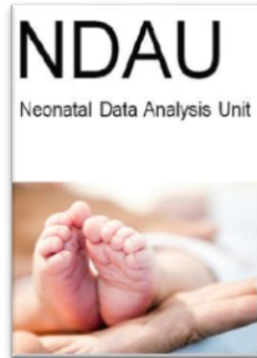
c/o Dr Kevin Goss

Leeds Centre for Newborn Care  
Leeds Children's Hospital  
Leeds  
LS1 3EX

[kevingoss@nhs.net](mailto:kevingoss@nhs.net)

18<sup>th</sup> March 2018

  
**National Institute for  
Health Research**



**Imperial College  
London**

Dear Dr

**Re: Your Trust claim for CRN Recruits for OPTI-SURF**

**OPTI-SURF: Optimising surfactant delivery for preterm babies with respiratory distress syndrome**  
(CMPS ID: 36652; IRAS ID: 237111)

Thank you for your continued interest in this project. This letter follows on from our original letter of information regarding this project, and details how your Trust can claim CRN accruals based on prospective admissions to your neonatal unit, for this CRN portfolio study.

- a) As this study sets a precedent for CRN recruits for projects such as this, should any aspect need clarification or consideration that we have not yet addressed, please feel free to contact us on the email addresses above.
- b) **Please share this letter and email with your Trust R&D department;** this will augment their notification of the study for CRN recruiting that is to be cascaded from your regional CRN team. Please note that the HRA considered this study not to require confirmation of capacity and capability with your R&D department.

To contribute to your CRN target accruals, your neonatal unit will need to

- a) ensure that parents are given information on the OPTI-SURF study (parent information leaflet attached). In the interests of uniformity, this is perhaps best done through routine inclusion of this leaflet into the general information given to parents when their baby is admitted to your neonatal unit

*and*

- b) Please assign an individual (research nurse, or local PI or clinical lead) who would be able to return the Study Recruitment Form in the 1st week of each month (form attached) containing information on number of babies born below 37+0 weeks gestation and admitted to your neonatal unit.

Please appoint a champion within your Unit who will take on the task of uploading all information and assign CRN recruits per individual Trust. CRN recruits from your Trust will then automatically be reflected on the CRN database. Please provide your Site ID number on the Study Recruitment Form. If you do not know this ID, please contact your R&D Department who will be able to provide you with your Site ID number. Without this ID we will not be able to assign your recruits.

Your neonatal unit should be able to claim CRN recruits with effect from the time of inclusion of the OPTI-SURF parent information leaflet generically into the admission information on your unit. The period for CRN recruiting will end on 31<sup>st</sup> December 2019.

Based on previous experience and, considering that all data is anonymised prior to reaching the study team, we think that the likelihood of parent opt-out is very slim. However, should any parent wish to opt-out their child's details (based on the Parent Information leaflet distributed to parents on your NNU) please may we request that this be communicated back to us at [ndau@imperial.ac.uk](mailto:ndau@imperial.ac.uk) on a monthly basis using the attached opt-out form. Please also offer parents, should they request it, our contact details for any further discussion in this regard.

Attached are the following

| Attachment                                                | Action needed                                                                                     |
|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| a) OPTI-SURF Protocol                                     | FYI                                                                                               |
| b) Parent leaflet and Poster for Unit                     | Leaflet into each admission pack for parents; one poster on NNU wall                              |
| c) CRN Recruitment form                                   | To be filled and returned monthly to <a href="mailto:ndau@imperial.ac.uk">ndau@imperial.ac.uk</a> |
| d) CRN recruitment algorithm                              | FYI                                                                                               |
| e) Opt-out form                                           | Only return if there are opt-outs                                                                 |
| f) A NDAU leaflet for information on how data may be used | FYI                                                                                               |

Yours Sincerely,



Dr Kevin Goss MB ChB PhD FRCPCH, Consultant Neonatologist, Leeds Teaching Hospitals NHS Trust

Collaborators: Prof N Modi and Dr C Gale, Imperial College London

Sponsor: Chiesi Limited

*Please note:* By placing the attached parent information leaflet in your neonatal unit admission packs, current babies managed on your neonatal unit, up until 31<sup>st</sup> December 2019, will count as CRN accruals towards your NIHR portfolio targets.