

Screening in the Neonatal Unit & Maternity Unit

- Screening can take place in both the **Neonatal Unit** and the **Maternity Unit**. Screening and eligibility checks can be completed by any trained and delegated Health Care Professional (however, final eligibility can only be confirmed by a delegated, medically trained doctor and ANNP)
- All infants in the Neonatal Unit (NNU) born between **34⁺⁰–38⁺⁶ weeks of gestation** with respiratory distress can be screened for eligibility. Parents with legal responsibility can be approached to discuss the study

- **Try to approach parents of infants with respiratory distress as early as possible**, even before they become eligible for SurfON. You can talk to them, show them the SurfON Introduction podcast (link below), and even take consent at this stage. This will give them time to consider participation if their baby goes on to need non-invasive respiratory support. Final eligibility will be checked once again prior to randomisation
- **Remember that any infant is eligible for SurfON if they need non-invasive respiratory support for increased work of breathing, regardless of whether they have an oxygen requirement or not.** Most late preterm and early term babies should not even need to come to a neonatal unit, so if a clinician decides their increased work of breathing warrants non-invasive respiratory support, this is clinically significant

- Women in the Maternity Unit who are expected to deliver between 34 and 36 weeks of gestation can also be screened for eligibility prior to delivery, at the clinical team's discretion. If a pregnant woman is screened and is interested in participation, please check after delivering the infant to confirm eligibility
- To ensure that potentially eligible infants and pregnant women are not missed, all Maternity Unit staff and Neonatal Unit staff should be familiar with the SurfON Study Protocol
- SurfON parent-friendly introduction podcast (<https://www.npeu.ox.ac.uk/surfon>) (or <https://youtu.be/y52cipynYiY>) can be utilised along with the Parent Information Leaflet (PIL) at this stage to provide information about the study
- To maximise awareness of the study, study information should be made widely available throughout the Neonatal Unit in the form of posters, banners and leaflets. SurfON stickers and recruitment posters can be used around the unit to act as visible reminders

If the participant is willing to participate and wishes to consent, follow instructions provided in Guidance Sheet 2 (Informed Consent).

The inclusion and exclusion criteria for the study are as follows:

Inclusion criteria

- Born at 34⁺⁰–38⁺⁶ weeks of gestation
- ≤ 24 hours old
- Respiratory distress defined as:
 - $\text{FiO}_2 \geq 0.3$ and < 0.45 needed to maintain $\text{SaO}_2 \geq 92\%$, **OR**
 - $\text{FiO}_2 < 0.3$, **with clinically significant work of breathing**
- Clinical decision to provide non-invasive respiratory support
- Written parental informed consent

Exclusion criteria

Infants cannot enter the study if ANY of the following apply:

- Major structural or chromosomal abnormality
- No realistic prospect of survival
- Prior intubation and/or surfactant administration
- Known or suspected hypoxic ischaemic encephalopathy
- Congenital abnormality of the upper or lower respiratory tract
- Known or suspected neuromuscular disorder

Screening Log

- A record of all those screened should be maintained. Please include all pregnant women or infants screened, even if they decline participation and be aware of any duplication in case pregnant women were screened before giving birth and had to be rescreened following infant birth
- Once a month, upload summary data for those screened on the SurfON randomisation website, by visiting (<https://rct.npeu.ox.ac.uk/surfon/login.php>), entering the site log in details and completing the screening tab
- A paper copy of the SurfON Screening Log is available in the Investigator Site File (ISF). These logs provide a more detailed record of individuals screened and are for internal site use only. Therefore paper logs are not expected to be submitted back to the study team, since screening information must be updated online on the Randomisation website on a monthly basis

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