GUIDANCE SHEET 4:
Trial Intervention

Infants can be randomised to either **Expectant Management** (or) **Early Surfactant Therapy.**

> In order to ensure sufficient separation between the two groups, it is essential that for infants in the early surfactant therapy group, **surfactant is given as early as possible, after meeting the inclusion criteria and being randomised**.

Expectant Management

Infants in the "expectant management" group should, where possible, **be maintained on non-invasive respiratory support alone**, at least until a more severe disease threshold is reached, defined as:

> Sustained (≥ 30 minutes) requirement for FiO2 ≥ 0.45 to maintain oxygen saturations (SaO2) ≥ 92%

This threshold has been determined by clinicians in line with current known variation in clinical practice. Any **deviation from this guidance should be at the discretion of the attending clinician**, following assessment of the infant's clinical condition.

Early Surfactant Therapy

For infants randomised to "Early Surfactant Therapy" group, **surfactant administration should occur as soon as possible after randomisation and within 24 hours of birth**.

Process for Administering Surfactant

- The recommended starting dose for the IMP is 100–200 mg/kg (1.25–2.5 ml/kg), as per the SmPC detailed in the SurfON Protocol.
- Please follow your local site policy for dosage including rounding to the nearest whole vial (120mg or 240mg), based on dose of 100mg/kg
- Surfactant should be administered in a **single** dose, as soon as possible after diagnosing respiratory distress syndrome and randomisation.
- The administration of surfactant is as per local site policy.
- Surfactant can be administered by a clinician or advanced nurse practitioner. However, final eligibility must always be confirmed by a clinician, in advance of administration.

Additional Respiratory Intervention

In either treatment group, surfactant may be given if the attending clinician deems this necessary. For those in the "Early Surfactant Therapy" group, this refers to surfactant that is additional to the single dose received as the trial intervention.

Where additional respiratory intervention and surfactant administration is provided, this should be documented in the online Surfactant Form in OpenClinica. Please see **Guidance Sheet 5: Case Report Forms** for further information on completing the Surfactant Form.

For either arm, if there are further clinical queries, please contact the SurfON Study Team. Contact details are provided in the Site Document Box and **Guidance Sheet 9: Emergency Queries**.

GUIDANCE SHEET 4

This study is funded by the National Institute for Health Research (NIHR) [Health Technology Assessment (HTA) (project reference 17/89/07)].
The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.