GUIDANCE SHEET 5:
Case Report Forms

Data collection

The majority of data for the SurfON study will be collected on electronic Case Report Forms (eCRFs) on the clinical database, OpenClinica©.

The following CRFs are mandatory and must be completed for all participants in the trial:

- Consent Form (paper)
- Randomisation (e-CRF – Randomisation website)
- Contact Details Form (e-CRF – Randomisation website)
- Trial Entry Form (eCRF – OpenClinica)
- Trial Intervention Form (eCRF – OpenClinica)
- Respiratory Support Log (paper and eCRF – OpenClinica)
- Outcomes Form (eCRF – OpenClinica)
- Mother's Entry & Discharge Questionnaire (paper), *if consent has been provided*

The following data collection forms may be required for some participants and will be completed as and when necessary:

- Surfactant Form (eCRF – Openclinica)
- Hospital Transfer Form (eCRF – Openclinica)
- Withdrawal Form (eCRF – Openclinica)
- SurfON Serious Adverse Event (SAE) Report Form (paper and eCRF – Openclinica)
- SurfON Incident and Deviation Form (paper)

eCRFS

Data entry on OpenClinica© can only be completed by **trained** and **delegated** individuals.

Log in details will be provided upon completion of training.

If you experience difficulties with OpenClinica©, please refer to the training podcasts on the SurfON website (https://www.npeu.ox.ac.uk/surfon/clinicians/training-materials) or contact the SurfON Study Team at surfon@npeu.ox.ac.uk.

Paper CRFs

All paper copy CRFs are kept in the SurfON Site Documents Box. Please contact the SurfON Study Team for further supplies.

If you make a mistake when filling out a form, strike through once and initial and date the correction, please **do not** use Tipp-ex or scribble out the mistake.

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Mandatory Case Report Forms

Trial Entry Form (eCRF)

- This form will be completed online once for each participant on OpenClinica. It is recommended that this form is completed as soon as practically possible after randomisation

Trial Intervention Form (eCRF)

- This form is completed on OpenClinica for all participants regardless of the treatment arm to which they are randomised
- For infants randomised to Expectant Management, details around the non-invasive respiratory support will be collected
- For infants randomised to Early Surfactant Therapy, details around the single dose of surfactant provided along with non-invasive respiratory support will be collected

Respiratory Support Log (Paper and eCRF)

Please ensure that this log is completed correctly without fail as it reports on the primary outcome for the study.

- The log is completed for all infants after randomisation, **for every day that the infant is on any form of respiratory support**, including oxygen only. A paper copy should be kept by the cot side for completion by clinical staff. Once complete the research nurse (or delegate) will be responsible for checking the accuracy of the data and entering into Openclinica.
- If the infant has no respiratory support, including additional oxygen, you can select 'Breathing in air' under the respiratory support column to report this. If an infant is recorded as **'Breathing in air'** for a full **24 hour** period, the Respiratory Support Log can stop being completed. It should be re-started, if further respiratory support becomes necessary.
- Please **do not stop** completing the respiratory support log as soon as the infant begins to 'breath in air'. As stated above, it must be completed for a full 24 hour period before being stopped.
- An **entry should be made every 4 hours** to record the infant's respiratory status for the previous 4-hour period. Please complete the date of first entry, study number and date of birth for the infant.

Every 4 hours you should record:

- **Type of respiratory support**, if any, during the previous four hours. Tick **EVERY** type of support used within the timeframe. It is understood that some of the timeframes provided in the log may not be used based on the time of randomisation

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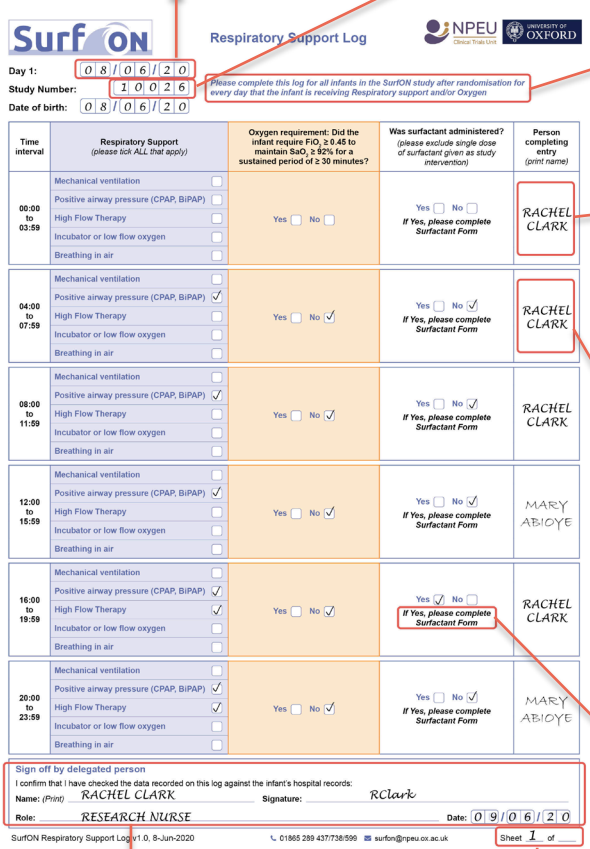
- For example, if the infant has been randomised on 8th May 2022 at 06.30, the date entry for day 1 at the top of the form will be 08/05/2022 and the first entry on the log will be made in timeframe, 04:00 to 07:59
- **Oxygen** requirement: Answer **'Yes'** if the infant has required $FiO_2 \geq 0.45$ to maintain $SaO_2 \geq 92\%$ for a sustained period of ≥ 30 minutes
- If the infant has had surfactant administered during the 4-hour period, complete Surfactant Form online in Openclinica. Please note that the single intervention dose of surfactant administered to those infants randomised to Early Surfactant Therapy **should not** be reported here. This information is recorded ONLY on the Trial Intervention Form
- Print your name next to the entry in case the delegated individual (e.g. lead research nurse) needs to clarify information supplied

This would usually be the same day of randomisation. Please ensure that the log is completed for all infants after randomisation.

Write down study number obtained from the Randomisation website. If there are multiples, ensure information is recorded correctly against the right study number. Mark as Twin One, Twin Two, for example, for ease.



SurfON Respiratory Support Log

NPEU OXFORD

Day 1: 08/06/20

Study Number: 10026

Date of birth: 08/06/20

Please complete this log for all infants in the SurfON study after randomisation for every day that the infant is receiving Respiratory support and/or Oxygen

Time interval	Respiratory Support (please tick ALL that apply)	Oxygen requirement: Did the infant require $FiO_2 \geq 0.45$ to maintain $SaO_2 \geq 92\%$ for a sustained period of ≥ 30 minutes?	Was surfactant administered? (please exclude single dose of surfactant given as study intervention)	Person completing entry (print name)
00:00 to 03:59	Mechanical ventilation ☐ Positive airway pressure (CPAP, BiPAP) ☐ High Flow Therapy ☐ Incubator or low flow oxygen ☐ Breathing in air ☐	Yes ☐ No ☐	Yes ☐ No ☐ If Yes, please complete Surfactant Form	RACHEL CLARK
04:00 to 07:59	Mechanical ventilation ☐ Positive airway pressure (CPAP, BiPAP) ☑ High Flow Therapy ☐ Incubator or low flow oxygen ☐ Breathing in air ☐	Yes ☐ No ☑	Yes ☐ No ☑ If Yes, please complete Surfactant Form	RACHEL CLARK
08:00 to 11:59	Mechanical ventilation ☐ Positive airway pressure (CPAP, BiPAP) ☑ High Flow Therapy ☐ Incubator or low flow oxygen ☐ Breathing in air ☐	Yes ☐ No ☑	Yes ☐ No ☑ If Yes, please complete Surfactant Form	RACHEL CLARK
12:00 to 15:59	Mechanical ventilation ☐ Positive airway pressure (CPAP, BiPAP) ☑ High Flow Therapy ☐ Incubator or low flow oxygen ☐ Breathing in air ☐	Yes ☐ No ☑	Yes ☐ No ☑ If Yes, please complete Surfactant Form	MARY ABIOYE
16:00 to 19:59	Mechanical ventilation ☐ Positive airway pressure (CPAP, BiPAP) ☑ High Flow Therapy ☑ Incubator or low flow oxygen ☐ Breathing in air ☐	Yes ☐ No ☑	Yes ☑ No ☐ If Yes, please complete Surfactant Form	RACHEL CLARK
20:00 to 23:59	Mechanical ventilation ☐ Positive airway pressure (CPAP, BiPAP) ☑ High Flow Therapy ☑ Incubator or low flow oxygen ☐ Breathing in air ☐	Yes ☐ No ☑	Yes ☐ No ☑ If Yes, please complete Surfactant Form	MARY ABIOYE

Sign off by delegated person

I confirm that I have checked the data recorded on this log against the infant's hospital records:

Name: (Print) RACHEL CLARK Signature: RClark

Role: RESEARCH NURSE Date: 09/06/20

SurfON Respiratory Support Log v1.0, 8-Jun-2020 01865 289 437/738/599 surfon@npeu.ox.ac.uk Sheet 1 of ___

Log should be completed for all infants randomised to either study arms. The log should be maintained until termination of all/any respiratory support or discharge home, whichever occurs first.

Logs can be completed by trained individuals. Notice that this particular time interval is empty, although the person completing the log at the time has printed their name in the last column.

In this example, the infant has been randomised on 8th Jun 20 at 6:30. The time of randomisation falls between 4:00 to 07:59. Therefore the first time interval is not applicable as details pertaining to respiratory support are only recorded after randomisation.

Note: When entering the data on OpenClinica, the first date and time field will be autopopulated based on the date and time of randomisation from the Randomisation website.

Note that a single dose of Surfactant given as part of study intervention is captured in the Trial Intervention Form.

Sign off should be completed only by delegated individuals.

Insert sheet numbers as completion of log occur. Each log can record up to 7 days worth of data. If in the event, you require the log after 7 days, please take a new log to continue data entry.

- The first entry for date and time will be prepopulated on the form online based on the date and time of randomisation
- The original paper log can be filed in the SurfON Data Collection File held at your site

Outcomes Form

- This form should be completed when the infant is discharged home
- In the event of death complete the relevant section in the Outcomes Form. If a post-mortem examination is being performed, please complete details pertaining to the cause of death when results are available. This should also be reported as an SAE, please refer to Guidance Sheet 6 Safety Incident Reporting

Mother's Trial Entry & Discharge Questionnaire

- If the mother has consented to complete the questionnaires, these should be provided initially at the point of randomisation and then again when the infant is discharged from hospital
- If a mother has a multiple births, a copy should be provided for each infant
- Ensure that the study number and date has been entered. Once complete, enter onto OpenClinica and keep a copy in the SurfON Data Collection File

Additional Forms

The following instructions are provided for those CRFs that may be required for some participants:

Surfactant Form

- Any **additional** doses of surfactant administered to the infant should be entered in this form. The first single dose of surfactant administered to infants soon after being randomised to Early Surfactant Therapy should be entered in Trial Intervention Form
- For infants randomised to Expectant Management, if a decision has been made to administer surfactant, details pertaining to administration should be completed using this form.

Transfer Form

- This form is completed for infants who are transferred to another hospital. This does not apply to any internal transfer that could occur, for example, transfer from NNU to surgical ward

If a transfer occurs as a result of an escalation of care, or because of a lack of intensive care capacity it must also be reported as a Serious Adverse Event (SAE). Transfer for a lower level of care (SCU) or for reasons unrelated to respiratory management does not need to be reported as an SAE.

- Transfer packs can be found in the Site Documents Box for those infants being transferred to another hospital. It is important to note that, although a transfer pack can be provided when the infant is transferred, the recruiting site is responsible for collecting all data related to the participant
- For further details regarding the process for hospital transfer, please refer to **Guidance Sheet 7: Hospital Transfers** and **Guidance sheet 10: Continuing Care Sites**

Withdrawal Form

- Please complete this form only if an infant is withdrawn from the trial
- As per Good Clinical Practice (GCP) guidance, the parent does not need to specify reasons for withdrawal. Where appropriate, the parent should be asked if they are happy for data collection to continue remotely without any direct involvement from them. Data collected up until the point of withdrawal cannot be withdrawn
- It is also noted in this form whether the parent would like to receive the results at the end of the study
- Remember to document the withdrawal form in the infant's medical notes
- For further information on how to report withdrawals, see **Guidance Sheet 8: Withdrawals**

SurfON Serious Adverse Event (SAE) Report Form

- Any site staff can report SAE using this form. See **Guidance Sheet 6: Safety & Incident Reporting** for further instructions

SurfON Incident and Deviation Form

- Deviations from Protocol, trial specific procedures, or GCP must be reported to the SurfON study team and documented using the Incident and Deviation form
- For guidance on how to report incidents please refer to **Guidance Sheet 6: Safety & Incident Reporting**

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