GUIDANCE SHEET 2:
Informed Consent

- Only trained and delegated staff can obtain informed consent. *Please ensure your local Principal Investigator (PI) has provided sign-off for this delegated responsibility for staff on the* **SurfON Site Delegation Log**
- Once infants have been identified (see **Guidance Sheet 1: Screening & Eligibility Assessment**), the clinical team should approach parents to discuss the study and request consent. This should happen promptly, once a clinical decision to provide non-invasive respiratory support has been made
- **Consent** and **randomisation** should be carried out **≤ 24 hours of birth**
- Parents should be given a copy of the Parent Information Leaflet (PIL) and given time to read this and discuss the study with the medical team. SurfON parent-friendly introduction podcast (https://www.npeu.ox.ac.uk/surfon (or) https://youtu.be/y52cipynYiY) can be utilised along with the PIL
- Written informed consent must be obtained before an infant can be randomised to SurfON
- Ensure that parents are aware that participation is voluntary and that consent may be withdrawn at any time without explanation, without this affecting the infant's quality of care. If they choose to withdraw, they will be asked if data collection can be completed
- The final assessment of eligibility of the infant for SurfON, must be confirmed by a **delegated medically trained doctor or ANNP** and documented in the medical records.

Who can take Consent?

Clinicians, ANNPs and nurses can obtain consent, however they **must** have GCP training, SurfON study training, and be delegated to take consent by the PI on the Delegation Log. This log is kept in the **Investigator Site File (ISF)**.

Who may give Consent?

Where possible, both parents should be involved in the consent process, however, the parent with legal parental responsibility for the infant must sign consent to the study.

Legal parental responsibility is defined as either:

- Birth mother
- Father/partner who meets one of the following criteria:
  - married or in a civil partnership with the child's birth mother
  - listed on the birth certificate, has a parental responsibility agreement with the mother, or has a parental responsibility order from a court

Where the mother is under 16 years of age, she may be approached for consent by the medical team, if she is determined to be competent according to the Fraser Guidelines.

If a parent's capacity to give informed, voluntary consent is in doubt, their infant should not be recruited. Where there is disagreement amongst parents regarding the infant's

participation, the infant should not be recruited. Where parents do not have a good understanding of English, sites may use the translation and interpreting services, which they routinely use in clinical practice to communicate the trial. However, study documents are only available in English language.

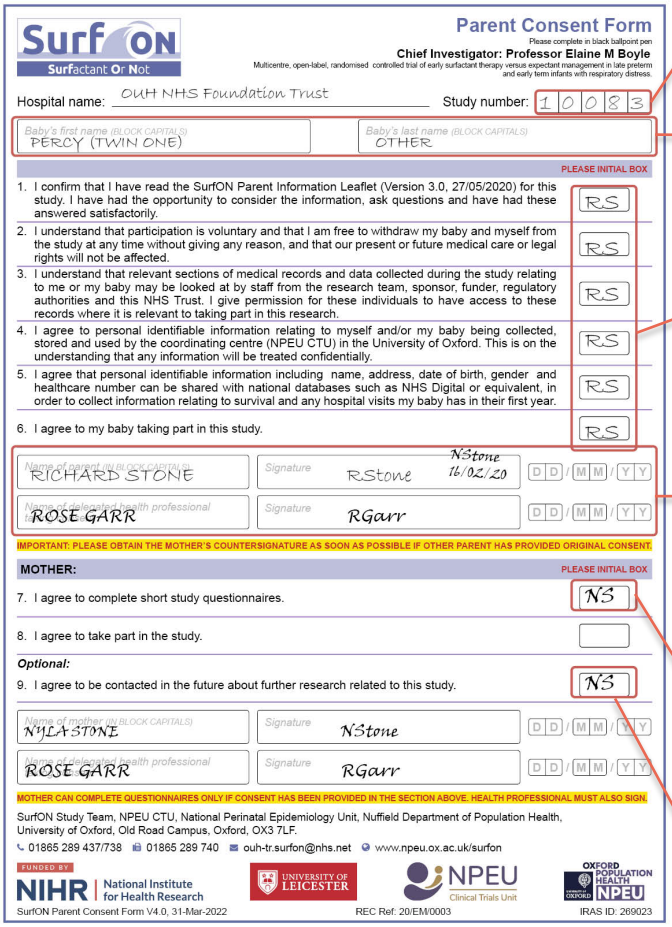
Key points to discuss with Parents:

- Ensure they are aware that participation is voluntary and that consent may be withdrawn at any time without explanation
- If they decide not to participate, it does not impact current or future NHS treatment and care
- We want to find out how best to treat breathing problems in babies born early
- If they agree to participate, their baby will have an equal chance of being in either study group:
    1) Receive a single dose of surfactant when they first start to need help breathing
    2) Expectant management, the doctor will see if their breathing improves with non-invasive support alone
- Regardless of which group their baby is in, they may still receive surfactant, if the doctor feels it becomes necessary
- Both groups are standard practice within the NHS, however practice varies across hospitals in the UK. We are conducting the study because we do not know which is most effective for babies in this particular age group
- Surfactant is routinely used in babies and there are **no additional risks** involved with taking part in the study. Whilst there may not be any direct benefit in taking part, participation may help improve future care for babies
- As part of data protection and confidentiality, it will not be possible to identify participants from any presentation, report or publication that may arise from this study. Data from medical records will be collected and kept securely as documented in the PIL
- Parents can choose to withdraw from the study at any point and do not have to give a reason
- Provide the opportunity for the parents to ask questions
- Document parental consent to take part in SurfON in the infant's medical notes

Completing the Consent Form

The consent form must be signed and dated by the parent(s) and the healthcare professional taking consent.

- Please complete the consent form in block capitals. Ensure all boxes are initialled/completed, the writing is clearly legible, and details have transferred through all copies of the form
- The professional taking consent should read through the consent form with the parent and the parent should **initial** *(not tick)* each box before signing and dating the form *(do not complete in advance)*
- Any healthcare professional signing this form **must** be delegated by the PI to take consent on the **SurfON Site Delegation Log**
- The dates for the parent and healthcare professional signatures must be the same. Parents must not be given a consent form to 'take away and sign'
- If a father signs, **a counter-signature from the mother must be obtained, in the first section, as soon as practically possible**
- The **second section** of the consent form labelled as **MOTHER** can only be completed and signed by the mother. It is important to note that if the mother is unable to provide consent in the second section, it **does not** preclude her infant from being included in the main study. Providing consent in the second section enables the mother to take part in completion of the study questionnaires provided once at randomisation and once at infant's discharge home
- The final point on the consent form, 'I agree to be contacted in the future about further research related to this study' is optional and therefore not mandatory for taking part in this study
- Separate consent forms will be required for twins, triplets, etc. Please make this clear on the consent form e.g. FIRST NAME (TWIN 1), LAST NAME as demonstrated in the example consent form
- Any corrections on the consent form must be made in a GCP-compliant manner (for eg- do not back date any corrections)



Parent Consent Form

Please complete in black ballpoint pen

Chief Investigator: Professor Elaine M Boyle

Multicentre, open-label, randomised controlled trial of early surfactant therapy versus expectant management in late preterm and early term infants with respiratory distress.

Hospital name: OUH NHS Foundation Trust Study number: 1 0 0 8 3

Baby's first name (BLOCK CAPITALS): PERCY (TWIN ONE) Baby's last name (BLOCK CAPITALS): OTHER

PLEASE INITIAL BOX

1. I confirm that I have read the SurfON Parent Information Leaflet (Version 3.0, 27/05/2020) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. RS
2. I understand that participation is voluntary and that I am free to withdraw my baby and myself from the study at any time without giving any reason, and that our present or future medical care or legal rights will not be affected. RS
3. I understand that relevant sections of medical records and data collected during the study relating to me or my baby may be looked at by staff from the research team, sponsor, funder, regulatory authorities and this NHS Trust. I give permission for these individuals to have access to these records where it is relevant to taking part in this research. RS
4. I agree to personal identifiable information relating to myself and/or my baby being collected, stored and used by the coordinating centre (NPEU CTU) in the University of Oxford. This is on the understanding that any information will be treated confidentially. RS
5. I agree that personal identifiable information including name, address, date of birth, gender and healthcare number can be shared with national databases such as NHS Digital or equivalent, in order to collect information relating to survival and any hospital visits my baby has in their first year. RS
6. I agree to my baby taking part in this study. RS

Name of parent (BLOCK CAPITALS): RICHARD STONE Signature: RStone 16/02/20 DD/MM/YY

Name of relevant health professional: ROSE GARR Signature: RGarr DD/MM/YY

IMPORTANT: PLEASE OBTAIN THE MOTHER'S COUNTERSIGNATURE AS SOON AS POSSIBLE IF OTHER PARENT HAS PROVIDED ORIGINAL CONSENT.

MOTHER: PLEASE INITIAL BOX

7. I agree to complete short study questionnaires. NS
8. I agree to take part in the study.

Optional:

9. I agree to be contacted in the future about further research related to this study. NS

Name of mother (BLOCK CAPITALS): NYLA STONE Signature: NStone DD/MM/YY

Name of relevant health professional: ROSE GARR Signature: RGarr DD/MM/YY

MOTHER CAN COMPLETE QUESTIONNAIRES ONLY IF CONSENT HAS BEEN PROVIDED IN THE SECTION ABOVE. HEALTH PROFESSIONAL MUST ALSO SIGN.

SurfON Study Team, NPEU CTU, National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Old Road Campus, Oxford, OX3 7LF.

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FUNDED BY NIHR | National Institute for Health Research

SurfON Parent Consent Form V4.0, 31-Mar-2022 REC Ref: 20/EM/0003 IRAS ID: 269023

ORIGINAL TO BE KEPT IN THE SITE FILE, 1x copy to Parent, 1x copy to SurfON Study Team, 1x copy in Baby's medical notes

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.

1. After consent, obtain a study number from the Randomisation website and write study number here.

2. Differentiate between multiples (for example, infants can be named as TWIN ONE, TWIN TWO). Where first name is not yet confirmed, write down as Baby.

3. Initial the box, not tick.

4. Both the parent providing consent and the health professional taking consent must be on the same date.

5. **Mother must counter-sign and date even if the other parent provides consent initially, as soon as practically possible.**

6. Consent to complete questionnaire by mother does not affect her infant from being included in the main study.

7. This is an optional consent option and can be left blank if they do not wish to be contacted in the future.

Allocation of Study Number

Following randomisation (see **Guidance Sheet 3: Randomisation**), the website-allocated Study number for the participant should be completed on the consent form.

Documentation

There are four copies of the consent form. Once complete, a clear scanned copy of the original should be emailed **ONLY** to ouh-tr.surfon@nhs.net from a nhs.net or trust email address.

Please use your nhs.net email id or trust email id to ensure patient confidentiality and end-to-end encryption.

The original consent form should be kept in the ISF, 1x copy to be given to the Parent and 1x copy to be stored in the infant's medical notes.

Administering Trial Entry Questionnaire

If the mother has provided consent to complete the questionnaire, please provide the Trial Entry Questionnaire as soon as informed consent is obtained and the baby has been randomised. The infant's study number should be entered on the Questionnaire after randomisation.

If the mother has delivered multiple infants, a questionnaire should be completed for each infant, for example, if the mother has delivered twins, she would complete 2x Trial Entry Questionnaires.

Once complete, this should be entered onto OpenClinica and the original filed in the Data Collection File.

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