Consent Form – Parent/Guardian

Interventional Study - *Parent/Guardian consenting on behalf of participant*

ANTENATAL (PROSPECTIVE) CONSENT

Title	The Positive End-Expiratory Pressure Levels during Resuscitation of Preterm Infants at Birth Trial
Short Title	The POLAR Trial
Protocol Number	60303
Project Sponsor	Murdoch Children's Research Institute
Principal Investigator	Dr David Quine
Associate Investigator(s)	N/A
Location	Royal Infirmary Edinburgh

Declaration by Parent/Guardian | Please initial the boxes to demonstrate consent

1. I have read Participant Information Sheet [V3.0; dated - 12 February 2024], or someone has read it to me in a language that I understand. I have had an opportunity to consider the information, ask questions and have had these answered satisfactorily. | Initial here if consenting to 1.

2. I understand that discussion of this study, and completion of a questionnaire, may be held in person, by telephone or similar remote digital videoconferencing platforms. | Initial here if consenting to 2.

3. I understand the purposes, procedures and risks of the research described in the project. | Initial here if consenting to 3.

4. **MOTHER TO INITIAL** I understand that relevant sections of medical records and data collected during the study relating to me may be looked at by staff from the research team, sponsor, 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. | Mother Initial here if consenting to 4.

5. I understand that relevant sections of medical records and data collected during the study relating to my baby may be looked at by staff from the research team, sponsor, 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. | Initial here if consenting to 5.

6. I understand that participation is voluntary and that I am free to withdraw my baby from the study at any time without giving any reason, and that my baby's present or future medical care or legal rights will not be affected.

Initial here if consenting to 6.

7. **MOTHER TO INITIAL** I understand that participation is voluntary and that I am free to withdraw myself from the study at any time without giving any reason, and that my present or future medical care or legal rights will not be affected.

Mother Initial here if consenting to 7.

8. I have read the POLAR privacy notice and know who to contact in case I have questions regarding the collection, use and/or storage of personal, identifiable data pertaining to my baby.

Initial here if consenting to 8.

9. **MOTHER TO INITIAL** I have read the POLAR privacy notice and know who to contact in case I have questions regarding the collection, use and/or storage of personal, identifiable data pertaining to me.

Mother Initial here if consenting to 9.

10. I agree to personal identifiable information relating to my baby being collected, stored, and used by the coordinating centre, MCRI in Australia and being stored by third party supplier Florence Healthcare on servers in Europe. This is on the understanding that any information will be treated confidentially.

Initial here if consenting to 10.

11. **MOTHER TO INITIAL** I agree to personal identifiable information relating to me being collected, stored, and used by the coordinating centre, MCRI in Australia and being stored by third party supplier Florence Healthcare on servers in Europe. This is on the understanding that any information will be treated confidentially.

Mother Initial here if consenting to 11.

12. I agree to my baby taking part in this study.

Initial here if consenting to 12.

13. I agree to the routine medical assessment data of how my baby has learned to walk, talk, and play at my baby's 24-month clinic visit at Royal Infirmary Edinburgh being de-identified and used for the POLAR trial.

Initial here if consenting to 13.

Name of Child (please print) _____
(After birth, if known)

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

Name of Child (please print) _____
(After birth, if known)
Name of Mother (please print) _____

Signature of Mother _____ Date _____

Name of Witness* to
Parent/Guardian's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Clinical Team Member†

I have given a verbal explanation of the research project; its procedures and risks and I believe that the parent/guardian has understood that explanation.

Name of Clinical Team
Member
† (please print) _____

Signature _____ Date _____

† A clinical team member must provide the explanation of, and information concerning, the research project.

Copy of this Consent Form to mother Y/N to ISF Y/N to medical records Y/N

PERMISSION TO COLLECT BASELINE DATA FROM MEDICAL RECORDS ONLY
(NO STUDY INTERVENTION)

We understand you do not wish to participate in the POLAR study. However, it would be helpful for us to understand how babies born prematurely respond to standard of care delivery room procedures. There will be no study intervention; the medical team will treat your baby according to routine care. We are asking for your permission to allow us to collect medical record information about your baby's health. We are also asking for your consent to collect your medical record information for this pregnancy:

a) The date and time of your baby's birth, the condition of your baby at birth, your baby's sex, weight and gestation, the mode of birth e.g. Caesarean section
b) The routine care your baby received immediately after birth and his/her response to care e.g. breathing support, amount of oxygen needed, medications
c) Your details: your race/ethnicity, age, previous pregnancies, and health during pregnancy.

Data collected from the medical chart will not contain any identified information.

Initial here — I give permission for data to be collected from my child's medical records, to be used for this research study and to be disclosed to the organisation running this study as detailed in Participant Information Sheet V3.0; dated - 12 February 2024.

Mother Initial here — **MOTHER TO INITIAL** I give permission for data to be collected from my medical records, to be used for this research study, and to be disclosed to the organisation running this study as detailed in Participant Information Sheet V3.0; dated - 12 February 2024.

Initial here — I understand that such information will remain confidential.

Initial here — I understand that relevant sections of medical records and data collected during the study relating to my baby may be looked at by staff from the research team, sponsor, 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.

Mother Initial here — **MOTHER TO INITIAL** I understand that relevant sections of medical records and data collected during the study relating to me may be looked at by staff from the research team, sponsor, 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.

Initial here

I agree to the use of this information, and I understand that I am free to withdraw permission at any time without affecting my baby's care. I understand that I will be given a signed copy of this document to keep.

Name of Child (please print) _____
(After birth, if known)
Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

Name of Child (please print) _____
(After birth, if known)
Name of Mother (please print) _____

Signature of Mother _____ Date _____

Name of Witness* to Parent/Guardian
Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Clinical Team Member†

Name of Study Doctor/
Researcher† (please print) _____

Signature _____ Date _____

† A clinical team member must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature

Copy of this Consent Form to mother Y/N to ISF Y/N to medical records Y/N