

**Informed Consent Form**  
**NOT APPROVED – FOR INFORMATION ONLY**  
 Please complete in black pen

Hospital name: \_\_\_\_\_ Study number:

Baby's first name

Baby's last name

**NEO-CIRC-003: An international study to investigate the effectiveness of dobutamine in supporting the hearts of premature babies soon after birth**

Please ***initial*** each box

1. I confirm that I have read and understand the information sheet (version \_\_\_\_\_ dated \_\_\_\_\_) for the above study and have had the opportunity to ask questions which have been answered satisfactorily.

2. I understand that participation of my baby in this study is voluntary and that I am free to withdraw my baby from the study at any time, without giving any reason, without the medical care or legal rights of my baby being affected.

2a. I agree that **all data collected until point of withdrawal** can be used as part of the study.

2b. I agree that **routine data collected after point of withdrawal** can be used as part of the study.

3. I understand that if my baby's doctor decides to start treatment my baby will be randomly allocated to one of the three study groups and a maximum of three small extra blood samples will be taken.

4. I understand that the information obtained during the conduct of this study is confidential, and my baby's data will be treated accordingly.

5. I understand sections of the medical notes of my baby may be looked at by responsible individuals from the study organisers or from regulatory authorities where it is relevant to my baby taking part in this research. I give permission for these individuals to have access to the records of my baby.

**6. Consent for sub studies**

The below statements are **optional**: If you **agree**: please **tick (✓) AND initial**. If you do **not agree**: please leave **blank**.  
 (You can say no to the below statements even if you would like your baby to take part in the main Study)

a) I agree for my baby to have the following additional observations as set out in the information leaflet:

Echo-D  NIRS  EEG

b) I agree for a short piece of my baby's umbilical cord to be stored for the duration of this trial.

7. I agree to my baby taking part in the above study.

**Please turn over for signatures.**

# NOT APPROVED – FOR INFORMATION ONLY

**Signatures:**

Name of parent/guardian

Name of parent/guardian

Signature

Signature

D D / M M / Y Y

D D / M M / Y Y

Name of clinician receiving consent

Signature

D D / M M / Y Y

1 for parent; 1 for site file; 1 to be kept with hospital notes