

Appendix A: Informed Consent Form

Multicenter, randomized non-inferiority trial of early treatment versus expectative management of patent ductus arteriosus in preterm infants.

We have been asked to consent to our child's participation in the scientific research study, called the BeNeDuctus Trial.

Child's name _____ Date of Birth ____ / ____ / ____

- I have been adequately informed about the research and have carefully read the patient information regarding the clinical study mentioned above. We have been allowed to pose questions about the study and these questions have been answered to our satisfaction. We have had ample opportunity to think about participating in the study
- I, the undersigned, reserve the right to withdraw our child from the study at any time. In accordance with the Code of Conduct drawn up by the Paediatric Association of the Netherlands, the study will be automatically discontinued in the event of any resistance.
- I know that certain parties will be allowed to inspect medical files of our child and the mother. These parties are mentioned in the Parent Information Form.
- I hereby consent the use of my child's and her/his mother's medical data for the purpose of this study, as mentioned in the Parent Information Form.
- I hereby consent the storage of the study data regarding my child for 15 years after the end of this study.
- I hereby consent the information of our general practitioner about participation in this study.
- I hereby consent to my child's participation in this study.
- I **do/do not*** give permission to contact me by postal mail or electronic mail (email) relating to follow up examinations.

Email address:

(*cross out what is not applicable)

Name parent/guardian Signature Date ____ / ____ / ____

Name parent/guardian Signature Date ____ / ____ / ____

I, the undersigned, hereby certify that the persons specified above have been informed about the aforementioned study both orally and in writing. I furthermore declare that any premature withdrawal from the study by any of the above persons will in no way affect the care to which he/she is entitled.

When information comes available during the study that might influence the already made decision of the parents/caretakers, I will inform them in a timely manner.

Name Signature Date ____ / ____ / ____

Position: _____