NEMO-1 study (dose finding stage)
Consent form

Project title NEMO1: An open label exploratory dose finding and pharmacokinetic clinical trial of bumetanide for the treatment of NEonatal seizure using Medication Off-patent

Name of chief investigator: Dr Ronit Pressler

Name of local principal investigator: Dr Sharon English, Consultant Neonatologist

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Please read the information below and then write your initials in the grey boxes.

1. I confirm that I have read and understood the information sheet dated _____/_____/____(version_____) for the above study and that I have had a chance to ask questions.
2. I confirm that I have had enough time to think about whether or not I want my baby to be included in the study.
3. I confirm that I am happy for my baby's anonymised video EEG data to be securely transferred to Cork, Ireland, via encrypted transfer media.
4. I confirm that I am happy for researchers in the NEMO team to have access to the results of my baby's routine hearing test, should that test be done after discharge from hospital.
5. I understand that I do not have to allow my baby to take part in the NEMO study and I can withdraw my baby from the study at any time, without giving any reason, without my baby's medical care or legal rights being affected.
6. I agree that if I choose to withdraw my baby from the study I give NEMO researchers permission to keep and use data or samples collected before this withdrawal. I understand that I can withdraw this permission at any time.
7. I understand that researchers involved in the NEMO study at this hospital_____ (hospital name) or regulatory authorities may look at parts of my baby's medical notes and the records of the labour and delivery of my baby. This will allow them to check that the trial has been run safely. I give permission for these individuals to have access to these records.
8. **I agree to allow my baby to take part in the NEMO study.**
9. I agree to allow small samples of my baby's blood to be retained for up to two years and then discarded after analysis.
10. I agree that the study team may contact me in the future regarding this study

Name of patient:	Birth date: _____/_____/_____	HN:
Name of parent or guardian	Signature of parent or guardian	Date _____/_____/_____
Independent witness	Witness signature	Date _____/_____/_____
Investigator (to be contacted if there are any problems)	Signature	Date _____/_____/_____