

Study Title: Digital recordings of heart sounds in babies during the Newborn Infant Physical Examination

Short title: The babyPHONO study

Chief Investigator: Dr. Neil Lawrence

Principal Investigator: Dr. Simon Clark

If you wish for your child to take part in 'The babyPHONO study', please read the participant information sheet (PIS_babyPHONO_echo_v2.0). Please write your initials next to each statement in the right-hand column below 'yes' if you agree or below 'no' if you do not agree, and sign and date the form at the end.

Participant Study Identification Number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Initial here for no:	Initial here for yes:
1	I confirm that I have read the relevant participant information sheet [PIS_babyPHONO_echo_v2.0] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2	I understand that taking part in this study will involve: a) The recording of my child's heart sounds using a digital stethoscope b) The recording of my child's heart rate, respiratory rate, and blood oxygen levels c) The completion of a short paper survey paper after (a) and (b) above d) The storing of pseudonymised images from my baby's echocardiogram for purposes of research analysis (pseudonymised means their personal details like name and date of birth will be removed) e) (a), (b), (c) and (d) above repeated if my child has a repeat echocardiogram before 3 months of age f) A follow-up telephone call after my child is 1 year of age to check if my child has been diagnosed with any heart conditions. This call will likely take less than 20 minutes.		
3	I understand that participation of my child is voluntary and that I am free to withdraw my child at any time without giving any reason, without my medical care or legal rights being affected.		
4	I understand that by choosing to participate as a volunteer in this research, this does not create a legally binding agreement nor is it intended to create an employment relationship with the University of Sheffield		
5	If I decide to withdraw my child from the study, I understand no further data will be collected. I understand that the research team can withdraw my data from the study, unless it has already been aggregated, shared or published in which case it will not be possible to withdraw my data.		
6	I understand that identifiable data (such as name) and relevant sections of my child's medical notes and/or data collected during the study may be reviewed by responsible individuals from the research team, the Sponsor (the University of Sheffield), the NHS Trust, or from regulatory authorities. I give permission for these individuals to have access to my child's records. The purpose of this access will be to establish the age of the baby (in hours) at each assessment, and to download images from echocardiogram scans from hospital systems after they've taken place.		
7	I understand and agree that anonymised data about my child may be used in publications, reports, presentations, web pages, and other research outputs. I understand that this anonymised and aggregated data will be available indefinitely, but that my child will not be identifiable in these outputs.		

Participant Study Identification Number:		Initial here for no:	Initial here for yes:
	<div style="display: flex; justify-content: space-around; width: 100px;"> <div style="border: 1px solid black; width: 30px; height: 30px;"></div> <div style="border: 1px solid black; width: 30px; height: 30px;"></div> <div style="border: 1px solid black; width: 30px; height: 30px;"></div> <div style="border: 1px solid black; width: 30px; height: 30px;"></div> <div style="border: 1px solid black; width: 30px; height: 30px;"></div> </div>		
8	OPTIONAL: I understand and agree for my child's individual pseudonymised information to be made available to other researchers, third parties or commercial parties on request for answering future research questions or the development or testing of healthcare technologies. You may still take part in the study if you do not consent for this type of data sharing (in this case please initial the box beneath the column 'no').		
9	I understand researchers or those at other organisations allowed by the research team to use the data will never know the identity of me or my baby, and no published research will ever reveal my identity.		
10	I understand that the heart sound recordings obtained from my child during this study are not being used to monitor their health and will not give them any medical benefit. The recording of heart sounds will not change the medical advice or tests that are offered.		
11	I understand that heart sound recordings obtained with the Eko CORE digital stethoscope are stored on a computer server in the United States prior to download onto NHS computers.		
12	I understand that clinicians involved in the study are informed not to enter patient identifiable data into the digital stethoscope application. Only the research study identifier will be entered into the stethoscope application. If a clinician taking part in the study accidentally enters any patient identifiable data into the application, that data will be deleted when the heart sound recordings are downloaded onto NHS computers.		
13	I understand that participation within this study does not alter any of the treatment or follow-up recommended for my child.		
14	I understand that records relating to my child will be kept confidential. No information will be released or printed that would identify my child without my permission unless required for hospital or research governance purposes.		
15	I understand and agree that the research team will securely store my identifiable details to contact me in future regarding this study (e.g. telephone/text/email) for up to 12 months after the end of the study. Identifiable details, including a copy of the consent form, will be available only to the research team, other than for purposes of monitoring and audit.		
16	I agree to be contacted for a telephone interview about my child's health after 1 year of age		
17	OPTIONAL: I agree to be emailed by the study team with updates about the studies progress and results. I will be able to opt out of these e-mails at any time.		
18	I agree for my child to take part in the above study		

Name of participant:

Date:

DD

MM

YYYY

Name of carer providing consent:

Signature of carer providing consent:

Name of research team member gaining consent:

Signature of research team member gaining consent: