



Bwrdd Iechyd Prifysol
Caerdydd a'r Fro
Cardiff and Vale
University Health Board



Parent Information Sheet

Invitation to complete questionnaire

FULL STUDY TITLE: **Respiratory Health Outcomes in Neonates (RHINO)**

CHIEF INVESTIGATOR: **Professor Sailesh Kotecha** (University Hospital of Wales, Heath Park, Cardiff)

Introduction

You may recall that you kindly completed a questionnaire for us in 2013 on the breathing and development of your child. When you completed the questionnaire, you were happy for us to contact you to consider participating in future studies.

We are now inviting you and your child to take part in a further research study. Before you decide if you want your child to take part, it is important that you understand why the research is being done and what it will mean for you and your child. Please take time to read the information leaflet. Please feel free to talk to others about the study and please ask us any questions that you may have or if anything is not clear.

What is the purpose of the study?

We know that children who are born prematurely have breathing problems like wheezing ("whistling in their chest") or shortness of breath but we do not know why children born prematurely have these breathing symptoms. Our first questionnaire study showed that many prematurely born children have symptoms affecting their breathing but we do not know if they improve with time so we would like to invite you to complete the questionnaire again.

Why has my child been chosen?

You may recall that you kindly completed a questionnaire for us in 2013 on the breathing and development of your child. When you completed the questionnaire, you were happy for us to contact you to consider participating in future studies.

We think it is important to determine if symptoms of children who were born prematurely change over time. We would therefore like to invite you again to complete the enclosed questionnaire to see how your child's symptoms have changed over the last 2 – 3 years.

Does my child have to take part?

No, taking part is completely voluntary. It is up to you and your child to decide whether or not to take part. A decision to leave the study, or a decision not to take part, will not change the standard of care you and your child receive now or in the future.

What will I be asked to do if we decide to take part?

If you decide to take part, please complete the enclosed questionnaire and return it to us in the pre-paid envelope.

The questionnaire should only take you 15-20 minutes to complete but please do not hesitate to contact the RHiNO team on telephone 029 2074 4187 or by email (rhino@cardiff.ac.uk) if you have any questions.

What are the other possible disadvantages and risks of taking part?

We do not feel there are any disadvantages and risks of taking part.

What are the possible benefits of taking part?

We are conducting this research so that we know how best to treat children born prematurely who have breathing problems and symptoms. Taking part will not help your child personally but the information we get might help to improve the treatment of children who were born prematurely in the future.

What will happen if my child or I don't want to carry on with the research?

You or your child can withdraw at any time. All data collected up until the time of withdrawal will be anonymised (this means that a number will be used instead of your child's name so that no-one will know the information is about them) and included in the study analysis, unless you specifically state otherwise.

What should I do if I have any concerns about the study?

If you have any questions about the study, please contact Professor Sailesh Kotecha or Dr Michael Cousins. If you remain unhappy and wish to complain formally, you can do this through NHS Complaints Procedure.

Will my child's taking part be kept confidential?

Yes. All of the information about your child's participation in this study will be kept confidential.

All information that is collected about you and your child during this study is considered to be confidential and giving this information to someone else ('a third party') is not allowed with the exceptions noted below. The paper files used to record information in this study will be labelled with a unique study number.

Your child's records will be checked by the RHiNO team at Cardiff University who are working with members of the North Wales Organisation for Randomised Trials in Health (NORTH) who are part of this study. All authorised individuals have a duty of confidentiality to you and your child as research participants and nothing that could reveal your child's identity will be disclosed outside the research site. All documents and files relating to the study will be stored confidentially for a maximum period of 25 years.

What will happen to the results of the research study?

The results will be published in medical journals and presented at medical conferences. Your child's confidentiality will be ensured at all times and they will not be identified in any publication. At the end of the study, the results can be made available to you (should you wish). They will also be published on the RHiNO website.

Who is organising and funding the research?

The study is sponsored by Cardiff University and funded by the Medical Research Council (MRC). Cardiff University have assigned the management of the study to the North Wales Organisation for Randomised Trials in Health (NORTH) at Bangor University.

Who has reviewed the study?

The study was approved by the South West-Central Bristol Research Ethics Committee (Ref 15/SW/0289). It has been registered with the International Standard Randomised Controlled Trial Number ISRCTN14767962.

Contact details:

Please do not hesitate to contact the RHiNO team on telephone 029 2074 4187 or by email (rhino@cardiff.ac.uk) if you have any questions. Further information is available at our website <http://rhino-health.org>.

Thank you for reading this information sheet