Participant Randomisation Number								

INFORMATION FOR PARENTS

Research Trial Entitled: **Timing Of Primary Surgery For Cleft Palate (TOPS)**

This trial will assess the timing of primary surgery in children with cleft palate.

Recruiting Centre Name: <Centre Name>

Recruiting Centre ID number: <Centre ID>

Dear Parent,

We would like to invite your child to take part in a trial of treatment for cleft palate. Before you decide whether you would like your child to take part we would like to explain to you why the research is being done and what it would involve for you.

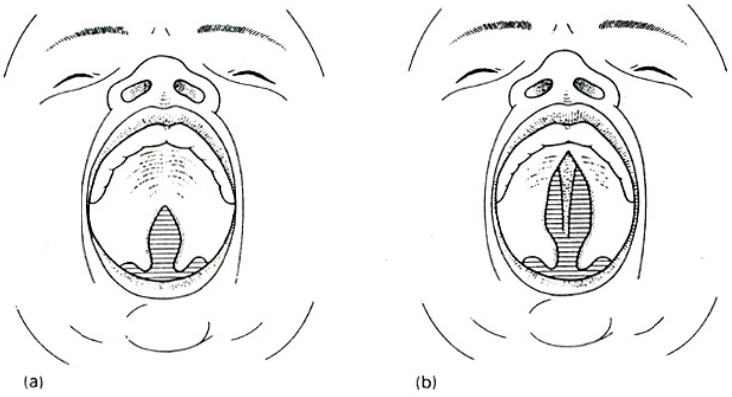
Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Talk to others about the trial if you wish.

Take time to decide whether or not you wish to take part.

Thank you for reading this information sheet.

1. What is the purpose of this trial?

The purpose of the trial is to find the best age at which to repair a cleft palate and give the child the best possible speech. Babies with cleft palate can have their surgery done at different times, usually before they are 18 months old.



The drawings above show (a) a cleft involving the soft palate and (b) a cleft involving the soft and hard palate.

Some centres prefer to repair a cleft palate when the baby is around 6 months old, others when the baby is around 12 months. However as yet, there is no reliable evidence to help surgeons decide whether one timing is better than another. The only way to find out is to make a careful comparison of different timings.

Therefore an international partnership has been formed to carry out a trial that will provide clearer evidence for selecting the timing of surgery for future babies with cleft palate. A total of 650 babies will be included in the trial.

2. Why has my child been invited to take part?

The TOPS Trial team at <Centre Name> is inviting all infants with cleft palate to join the trial.

3. Does my child have to take part?

No, the research is voluntary. It is up to you to decide. We will describe the trial and go through this information sheet, which we will then give to you. You will be given time to think about the trial. Should you decide that you would like your child to participate we will ask you to sign a consent form. You are free to withdraw your child from the trial at any time, without giving a reason. This would not affect the standard of care your child receives.

If you decide that you do not want your child to participate in the TOPS trial the care they will receive will not be affected and will be the standard care provided at <Centre Name> with your child's surgery usually taking place at suitable time between the ages of 6 and 18months.

4. What will happen if I choose for my child to take part?

Babies with a cleft palate taking part in the trial will be divided into two groups. One group will have surgery at 6 months and one at 12 months. All will have surgery performed according to the same well-established technique and your cleft palate team will discuss the surgery with you at a routine clinic appointment. The age group that each baby goes in to will be decided by chance using a computer system, this is called randomisation and will ensure that there are equal numbers in each of the groups.

Before the operation a full physical examination will be done and a family history will be taken. During the operation a photograph and an impression of your child's mouth (called a maxillary arch impression) will be taken and a blood sample will be collected unless this has been taken previously. If a blood sample cannot be taken at surgery we will ask your permission to take it at another suitable time, for example, when your child is having a blood sample for another reason. The blood will be used to look for genetic markers which may be associated with cleft palate, these tests are routinely performed as part of your infants care and you will be informed of the results.

In all other respects the treatment and follow-up care for babies with cleft palate will be the same for those taking part in the trial and those who are not. The records used to make the comparison are the standard follow-up records and checks that all babies with cleft palate should have, although the appointments with the speech therapist at age 1, 3, and 5 years may take 20-30 minutes longer. We would also like to take a photograph of your child and make an impression of his/her teeth when they have their 5 year follow up visit.

5. What will I have to do if my child takes part?

We would like you to keep all the usual appointments made to see the cleft palate team.

6. What are the alternatives for diagnosis or treatment?

As mentioned above, there are several different timings in use, but no evidence that one is better than another.

7. Are there any possible disadvantages and risks or side-effects of taking part?

The timing and techniques in the trial are standard practice, with no known differences in risk to your child.

8. What are the possible benefits of taking part?

The results we obtain from our trial of the surgical timing are unlikely to provide any direct benefit for your baby. However we hope that these results will help our team and other teams make the best possible decisions in providing treatment for future babies. The results of the genetic tests may help to identify a specific cause for the cleft palate in your family and if so we will be able to provide you with further information and offer testing to members of your extended family.

9. What will happen if something goes wrong?

In the event that something does go wrong due to negligence then you may have grounds for legal action for compensation against <Centre Name> but you may have to pay your legal costs.

If you have a concern about any aspect of the trial you should ask to speak to a member of the cleft team who will do their best to answer your questions (contact number below).

The normal complaints mechanisms in place at <Centre Name> will still be available to you. Details can be obtained from the hospital.

10. What happens if I want to withdraw my child from the trial?

You may withdraw your child from the trial at any time if you wish. If you withdraw your child from the trial your child's ongoing and future care will not be affected by your decision.

11. Will my child taking part in the trial be kept confidential?

All information that is collected about you and your child during the course of the trial will be kept strictly confidential, and any information that leaves <centre name> will have your child's name and address removed so that your child cannot be recognised. However, we would like to ask your permission for a copy of the consent form, which will have your and your child's name on it, to be sent to the Data Coordinating Centre at the University of Liverpool.

All legal requirements applying to research of this kind will be strictly adhered to.

12. What will happen to the blood sample?

This sample will be analysed to see whether there is any genetic condition that may be associated with the cleft. If changes are identified on the blood tests the findings will be discussed with you and you will be offered the opportunity to discuss them with a paediatrician or clinical geneticist, should you wish. These blood tests are part of the routine care offered by <centre name>.

The blood samples will not be stored as part of the trial and we will not use them for any other tests.

13. What will happen to the results of the trial?

When the last patients in the trial reach age 5, and their speech has been assessed, we will analyse the results of the trial. No matter what the conclusions are, we will present the findings at professional meetings and in the appropriate medical journals so that as many future patients as possible will benefit. Naturally, no individual children will be identified in such reports. If you would like a copy of the final trial report you can indicate so on the consent letter.

14. Who is organising and funding the research?

The trial has been planned by an international collaboration of cleft specialists. The Administrative Centre for the trial is the University of Manchester, UK, the Data Coordinating Centre for the trial is the University of Liverpool, UK. The Administrative Centre will be responsible for the storage of your child's maxillary/dental impressions. The Data Coordinating Centre will store the information recorded, for the trial, by your child's cleft palate team, this data together with the impressions stored at Manchester will have your child's name removed. The trial is being funded by the National Institute of Dental and Craniofacial Research in the USA.

15. Who has reviewed the trial?

All research is looked at by an independent group of people called a research ethics committee to protect you and your child's safety, rights, wellbeing, and dignity. This trial has been reviewed and given a favourable opinion by Yorkshire and the Humber – Leeds East Research Ethics Committee

Contact for further information

If you would like more information about the trial please contact:

<Site Coordinator Name>

<Site coordinator Contact Number>

Participant Randomisation Number								

CONSENT FORM

Research Trial Entitled: **Timing Of Primary Surgery For Cleft Palate (TOPS)**

Centre Name: <Centre Name/s>

Name of Researchers: <Names of all researches in involved centres>

Initial box

1. I confirm that I have read and understand the information sheet (version number 3.0, dated, 01-May-2013) for the above trial. I have had the opportunity to consider the information and ask questions and have had these answered satisfactorily. ☐

2. I understand that the participation of my child's is voluntary and that I and my child are free to withdraw at any time, without giving any reason, without our medical care or legal rights being affected. ☐

3. I understand that relevant sections of my child's medical notes and data collected during the trial may be looked at by individuals from the research team, representatives of the sponsor, from regulatory authorities or from the organization delivering healthcare, where it is relevant to my child participating in this research. I give permission for these individuals to have access to my child's records. ☐

4. I agree to copies of my consent form to be sent to the Data Coordinating Centre at the University of Liverpool ☐

5. I agree to photographs of my child being taken for the purposes of the trial. ☐

6. I agree to audio and video recordings of my child being made for the assessment of speech development. ☐

7. I agree to my child having impressions of their mouth and teeth (maxillary arch/dental impressions) for the purposes of the trial. ☐

8. I agree to relevant information from routine genetic tests to be used by the trial team. ☐

9. I agree to a small blood sample being taken during surgery, or at another appropriate time, for genetic tests if they have not already been performed. ☐

10. I agree to be contacted by the cleft palate team using the information provided for myself and other relevant contacts or to be contacted using my NHS or national identification number where appropriate. ☐

11 I agree to my child's GP or local physician being informed about his/her participation in the trial where appropriate. ☐

12. I agree to take part in the above trial and I also agree for my child to take part in the above trial. ☐

13. I agree/do not agree (delete as appropriate) to be contacted by other researchers to participate in other ethically approved studies in cleft and lip palate. ☐

14. I would like/ would not like (delete as appropriate) a copy of the final report. ☐

_____	_____	
Name of Child	Child's Date of Birth (dd-mm-yyyy)	
_____	_____	_____
Name of Parent/Guardian	Signature of Parent/Guardian	Date (dd-mm-yyyy)
_____	_____	_____
Name of Researcher	Signature of Researcher	Date (dd-mm-yyyy)

When completed, 2 copies need to be made, 1 for the participant, 1 for the investigator site file and the original must be kept in the medical notes. A copy of the consent form only should be faxed to the Data Coordinating Centre on +44 (0) 151 282 4721