Centre Name		Centre ID		TOPS additional information and consent form V1.0 30-March-2015

Important changes to the TOPS trial

Dear Parent,

The TOPS trial that you and your child are taking part in will assess the timing of primary surgery in children with cleft palate. We have made some changes since you agreed to be in the trial and would like to let you know about these and to check you are happy with them. There are two changes aimed at improving the data we collect about your child's speech:

1. We would like to send a questionnaire to other therapists outside of <centre name> who have provided speech therapy for your child. This questionnaire will ask how many and what type of speech therapy sessions your child has had.

2. When you attend for your child's age 5 speech follow up we will ask you to complete a short questionnaire about how well your child is understood by others. The questionnaire has 7 questions and takes about 5 minutes to complete.

These changes have been looked at and approved by an independent group of people called a research ethics committee (The Yorkshire and the Humber– Leeds East Research Ethics Committee).

Please tell us if you are happy with each of these changes, or not, by completing the section below and returning this form in the addressed envelope provided. We have included a copy of the information for you to keep.

If you would like more information about these changes before you make a decision please contact:

<Site Coordinator Name>, <Site coordinator Contact Number>

Please tick ✓ and initial in the spaces below

	Tick (✓)	**Initials**
I agree to my local speech therapist being contacted about my child's speech therapy sessions.	Yes ☐ No ☐	
I am happy with the changes made to the 5 year follow up visit and understand I will be asked to complete a short, 5 minute, questionnaire when I attend.	Yes ☐ No ☐	

Your name	

Your signature		**Today's Date**	

Your child's name		**Your child's date of birth**	

To be completed by the research team

Randomisation Number								

Date sent/given to parent	d	d	m	m	y	y	Sent by (Signature)	
Date received at site	d	d	m	m	y	y	Received by (Signature)	

When complete, 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