



# NEWSLETTER

December 2015, Issue 11



## Update: TOPS trial team at the Data Coordinating Centre in Liverpool

You probably know already that we have had some staff changes to the team at the Data Coordinating Centre (DCC). There is a new Data Manager: Jonathan McKell who has taken over from Callam Weldon, and is taking care of the speech recordings. Additionally there is a new trial coordinator assistant: Katie Blundell. Cath Spowart has also taken over TOPS from Nicola Harman who is on maternity leave.

## Speech Group Meeting

The recent speech group rating calibration meeting in Manchester (Nov. 9-11) has been very successful. The first 12 month rating meeting will now take place in Manchester in March 2016.



## TOPS Substantial Amendment

The TOPS Substantial Amendment 3 has been approved by all UK sites and is currently being processed internationally

The main parts of this amendment are: a short questionnaire for the participants' parents (Intelligibility in Context (ICS) questionnaire) and a new additional supplementary Parent Information and Consent form, which is to take consent for collecting information and additional data on speech using the ICS questionnaire.

This amendment also includes:

- Protocol V4.0
- Pilot PISC V4.0
- STSD #1 Trial Centres V3.3
- CRF Form 13: 5 Year Assessment V3.0

We will send you these documents as the amendment is approved by your site.

## Christmas Closure Information

The TOPS Data Coordinating Centre at the University of Liverpool is closed from 5pm on the 23<sup>rd</sup> December 2015 and re-opens 4th January 2016.

There will be office cover available on 29<sup>th</sup> December for the management of safety reporting (Serious Adverse Events and Unanticipated Problems) and dealing with other urgent enquiries.

If you have an enquiry requiring a response on 29<sup>th</sup> December please either call 0151 282 4726 (answer phone available) or alternatively email [ctaylor7@liverpool.ac.uk](mailto:ctaylor7@liverpool.ac.uk)

Merry Christmas!

Feliz Natal!

Glædelig Jul!

God Jul!



**Thank you for your continued hard work and support on the study.**