

Supplementary Material No. 4: TOPS Trial Committees

1.1 Trial Management Group (TMG)

The Trial Management Group (TMG) comprises members of the Administrative and Data Coordinating Centres and representatives of the core speech group and National Institute of Dental and Craniofacial Research. The Trial Management Group is responsible for the day-to-day running and management of the trial. The Trial Management Group will meet monthly in the first instance and a minimum of four times a year, attendance at Trial Management Group meetings will be by teleconference. Other meetings will be held by teleconference call as needed. Telephone and email will be a primary means of daily communication between members of the Trial Management Group.

1.2 Trial Steering Committee (TSC)

The Trial Steering Committee will be composed of the trial investigators, members of the trial team at the Administrative and Data Coordinating Centres in addition to an independent chairperson and independent experts in the field of cleft palate surgery, speech therapy and biostatistics.

The role of the Trial Steering Committee is to provide overall supervision for the trial and provide advice through its independent Chairman. The ultimate decision for the continuation of the trial lies with the Trial Steering Committee. The Trial Steering Committee will meet at least annually by teleconference. Other meetings will be held by bimonthly teleconference call as needed. E-mail will be a primary means of communication between members of the Trial Steering Committee. The Trial Steering Committee may also make recommendations to the Funder who may withdraw funding of the study.

1.3 Data and Safety Monitoring Board (DSMB)

The composition of the Data and Safety Monitoring Board will be decided by the National Institute of Health / National Institute of Dental and Craniofacial Research (NIH/NIDCR) and the initial committee meeting will be convened prior to the trial commencing.

The Data and Safety Monitoring Board is an independent (should not be involved with the trial in any other way or have some competing interest that could impact on the trial) multidisciplinary group consisting of at least one statistician and at least one clinician that,

collectively, have experience in the management of children with cleft palate and in the conduct of randomised controlled trials.

The Data and Safety Monitoring Board will be responsible for reviewing and assessing recruitment, interim monitoring of safety, trial conduct and external data.

The full terms of reference and roles of the Data and Safety Monitoring Board are detailed in the Data and Safety Monitoring Board Charter and a copy of the open minutes from each DSMB meeting will be provided to the Program Official at National Institute of Dental and Craniofacial Research.