



Terms of Reference and Guidelines for ASTN Research Committee

Composition

The Research Committee is made up of the following members, appointed by the Executive:

- 2 Chief Investigators on the NHMRC Enabling Grant
- 4 other researchers, either Associated Investigators named in the Enabling Grant, or others with relevant clinical trials expertise
- Australasian Sleep Trials Network consultant biostatistician
- Australasian Sleep Trials Network consultant health economist
- 1 Consumer

The Chairperson of the Research Committee is appointed by the ASTN Executive. The Committee may invite additional people with special skills to join them as required.

Responsibilities

The ASTN Research Committee will be responsible for assessing the merits of all study proposals and making a recommendation to the ASTN Executive.

The Research Committee will also work with the Executive to plan the programme for biannual Open Forum meetings.

1. ASTN-Supported Studies

Process for initial and final assessments

The Research Committee will:

- Recommend to Executive whether or not a new proposal should receive provisional support from the Network and the principal investigators be asked to further develop the proposal
- Recommend to principal investigators protocol changes/refinements to enhance the quality of the proposal and its chances of success with external funding agencies
- In consultation with the Executive, engage the services as required of the Australasian Sleep Trials Network biostatistician, health economist and National Project Officer or other resources to assist the principal investigators in refining and improving the proposal
- Review final draft Australasian Sleep Trials Network-Supported Study proposals
- Recommend to the Executive whether or not to proceed with the study

- Recommend to the Executive which Network resources should be allocated on an ongoing basis to ensure the success of the study e.g. recruitment infrastructure, biostatistician or health economics advice, central data management, inter-laboratory quality control, safety monitoring

Assessment criteria

The Research Committee judges proposals on the basis of:

- The fit of the study to the Australasian Sleep Trials Network Mission Statement
- Scientific rigor and merit of the research plan
- Track record and potential of the research team
- Feasibility of successfully concluding the study bearing in mind issues such as access to suitable research subjects and competing demands on Australasian Sleep Trials Network resources

Study proposals must be developed in accordance with Good Clinical Research Practice, as follows.

Guidelines and generic protocol formats that include:

- Nominated principal investigators and institutions
- Hypothesis, rationale and study aim
- Study population – sample size calculations, pilot data, inclusion and exclusion criteria
- Methodology – concealment, randomization, measurements, timelines, statistical analyses
- Safety – data monitoring and safety, termination criteria, adverse event reporting
- Regulatory section – ethics submission and consent forms, data capture methodology, and documentation requirements including NHMRC clinical trials registration

The Research Committee should not provide full scientific review or make changes to the protocol, especially in the early phases of the review/endorsement process. In the initial review process the Committee is primarily looking for potential. Investigators themselves should be encouraged to improve the protocol, based on statistical, health economist, peer and collaborator input.

Trials designed by commercial companies or research groups outside Australasia would not normally be eligible to apply under this category.

In general, at least three research centres should be involved.

The proposal can be to conduct a cohort study or a clinical trial of a therapy, educational, public health intervention or diagnostic method.

Support for ASTN Supported Studies

Once in-principle approval is given by the Australasian Sleep Trials Network Research Committee and Executive, these studies will receive major and ongoing administrative and scientific support of the network. Network resources will be applied to assist with the design and development of the proposal, with applications to external granting agencies, and with the conduct of the study including recruitment,

data management, statistics and data analysis, safety monitoring and the publication of the results in high impact journals.

- Executive has the right to formally withdraw ASTN endorsement of the study at any time if it has reason to believe that the study is not progressing in accordance with Good Clinical Research Practice or the integrity of the project is seriously compromised for whatever reason.

- A brief annual report should be provided to the Executive on progress of trial

- ASTN Executive will review all manuscripts and reports arising from such studies ahead of publication, reserves the right to make comments, and should be acknowledged in these publications.

Conflict of interest

Members of the Research Committee or Executive who have any involvement with the proposed trial or have any conflict of interest with the researcher(s) will be excluded from the decision making processes.

2. ASTN-Endorsed Studies

An individual or group of individuals develops these studies and is responsible for their conduct. Commercial companies or international research groups can apply through Australian or New Zealand- based principal investigator(s) to the ASTN for clinical trial endorsement.

The ASTN will normally only endorse studies prospectively - i.e. before they commence and not during enrolment or following completion. However, success with NHMRC funding for a multicentre study in sleep health gives ASTN endorsement (if not previously obtained), and access to some ASTN resources.

Fees may be charged for assessment of studies submitted for endorsement and for ongoing services provided by the Network.

Process for assessment

The Research Committee will supervise the protocol review by at least 2 nominated individuals with appropriate expertise and make a recommendation for endorsement or non-endorsement to the Executive.

The Research Committee should not provide full scientific review or make changes to the protocol, especially in the early phases of the review/endorsement process. In the initial review process the Committee is primarily looking for potential. Investigators themselves should be encouraged to improve the protocol, based on statistical, health economist, peer and collaborator input.

Assessment criteria

Studies put forward to the ASTN for endorsement must:

- accord with the mission of the ASTN
- address a fundamental question related to sleep health
- meet the ASTN's standards with respect to scientific quality, ethics and conflict of interest.

Such studies should not compromise access of Australasian investigator-driven proposals to the ASTN or compromise the overall quality or availability of the ASTN resource.

Support for ASTN Endorsed Studies

The Research Committee will recommend to the Executive what, if any, ASTN resources be made available to the investigators to facilitate the study.

The Executive may agree to allocate some ASTN administrative or scientific resources towards endorsed studies - e.g. to help publicize the study, recruit centres, provide independent advice on study design, and limited consultant input for study design or analysis. More extended access to ASTN consultants can be extended if the investigator's institution pays half the consultancy fee.

The Principal Investigator of an ASTN-endorsed study is required to provide a brief report to the ASTN Executive on the progress of the trial at the end of each year. The Executive has the right to formally withdraw ASTN endorsement of the study at any time if it has reason to believe that the study is not progressing in accordance with Good Clinical Research Practice or the integrity of the project is seriously compromised for whatever reason.

The data of ASTN-endorsed studies are owned by the investigators. ASTN reserves the right to comment on all manuscripts and reports arising from such studies ahead of publication and to be acknowledged in all publications.

Investigators can also apply for assistance to conduct pilot studies to provide data to justify bigger multicentre studies.

Conflict of interest

Members of the Research Committee and Executive who have any involvement with the proposed trial or have any conflict of interest with the researchers or commercial sponsors will be excluded from the decision making.

Approved by ASTN Executive 01/02/2007.

Updated 27/04/07 to reflect decisions made at Executive committee 24/03/07