
MISSION

The Australasian Sleep Trials Network now has a clearly articulated mission:

The mission of the Australasian Sleep Trials Network is to conduct and facilitate clinical trials of national and international significance that will have a major impact on sleep health. It will achieve this mission principally through investigator driven trials, funded by government or industry.

PERTH OPEN FORUM

A good way to find out more about the Sleep Trials Network, and contribute to its development, is to register for the Perth Open Forum. The Open Forum will be held on the afternoon of 4 October as part of the Australasian Sleep Association and Australasian Sleep Technologists Association (ASA/ASTA) 2006 annual meeting.

At the Open Forum there will be a presentation outlining early ideas about how the Network should operate, and asking for researcher input.

A highlight will be discussion about the important questions in sleep health with experts from major fields of research in sleep health.

There are two ways to register for the Open Forum. If you are planning to register for the ASA/ASTA meeting, you can register for the Open Forum at the same time. Otherwise, let us know that you are planning to attend by sending an email to: melanie.harris@rgh.sa.gov.au

IN THIS ISSUE

Mission.....	1
Perth Open Forum.....	1
Your Questions Answered	2
Biostatistics & Health	
Economics Services.....	5
Obstructive Sleep Apnea &	
Cardiovascular Events Trial	5

YOUR QUESTIONS ANSWERED

The following information is provided in response to questions that have arisen during the development of the Sleep Trials Network. Please let us know if you have questions that aren't answered here.

I haven't time to read lots of documentation. Briefly, what is the purpose of the Sleep Trials Network and how does it achieve this purpose?

The mission of the Australasian Sleep Trials Network is to conduct and facilitate clinical trials of national and international significance that will have a major impact on sleep health. It will achieve this mission principally through investigator driven trials, funded by government or industry.

The network isn't funded to provide direct grants for multicentre trials. Instead, it will provide resources so that researchers can submit very competitive, well worked proposals to existing granting sources. It will also put potential collaborators in touch, so that trials have enough sites for speedy recruitment of target numbers of subjects.

Does the Sleep Trials Network committee aim to oversee all clinical sleep health research proposals in Australia?

A Sleep Trials Network committee (the Protocol Group) will look only at proposals that researchers choose to bring to the Network, and only at proposals for multicentre trials. The aim is to provide support and infrastructure to strengthen and advance sleep health trials in our region, rather than to take on an overseeing role.

What are the benefits of bringing my proposal for a multicentre study to the Sleep Trials Network?

The Network can help you put together an impressive and competitive protocol to improve your chances of funding success. Expert biostatistical and clinical trial design advice and special expertise in outcome measurement are provided by the Network. The protocol may be strengthened also by including economic measures, or a genomics element, again using experts provided by the Network. Input from peers can further iron out potential problems before the protocol is submitted for funding.

Contact with potential collaborators is another benefit. Bringing in several other centres might be the best way to achieve a big enough sample size for a properly powered study, or when the study focuses on a rare condition. Other centres may already be planning a similar study and a combined study may receive funding ahead of two smaller competing studies.

How can the Sleep Trials Network help my group get funding for a multicentre study?

Rather than funding large studies directly, the Network provides expertise in areas such as biostatistics, study design, health economics, outcome measurement and genomics, so that collaborative groups can take compelling proposals to funding bodies. Network infrastructure may also be committed for the conduct of a study (e.g. for recruitment, outcome measurement, data management or analysis), further strengthening the funding proposal. In addition, Network members can provide links to likely sources of funding.

Why should I share my research ideas with others in the Network?

One view is that confidentiality is unlikely to be a barrier for most researchers bringing proposals to the Network. Proposals well suited to the Network are those which address well-established problems. Researchers would approach the Network for refinement of a study protocol and for collaborators with relevant experience and a particular desire to solve the problem. Novel, early research ideas will rarely need or justify testing through large multicentre trials and will therefore be outside the province of the Network.

There may be occasions when confidentiality is important. A policy and mechanism for confidentiality within the Sleep Trials Network are currently being discussed. Your contribution to these discussions is welcome.

Why have a committee to vet research proposals?

The role of the Protocol Group is to manage the use of Network resources. As the Sleep Trials Network has limited funding to support the development of protocols, the committee provides a mechanism for selecting which studies will get that support.

Are there checks and balances to ensure fairness in the committee's selection of studies to receive support from the Network?

Selection criteria for selecting studies to receive support are currently being drafted and will be openly available for comment.

When studies are assessed as not meeting the criteria, the Protocol Group will give researchers reasons for their decision. If researchers wish, the Protocol Group will discuss ways of developing the research so that it fits the mission of the Sleep Trials Network. Protocol Group decisions will be reviewed by an independent review and appeals body. Comments on the nature of this review body are welcome.

I see from the first newsletter that there is a large number of Associate Investigators on the Enabling Grant. What is their role?

The Associate Investigators (AI) form a consultative group of researchers from the range of sleep disciplines and both within and outside of the Australia New Zealand region. The Chief Investigators (CI) have sought AI opinions as they develop the operations of the Network, by inviting AIs to planning meetings where possible, and by circulating draft documents. AI contributions to decision making will continue. For example, an AI will be invited onto the executive group, rotating each year.

It is also hoped that AIs will form an important link between the Sleep Trials Network and the sleep research community to increase participation in the Network.

I'm not a Chief Investigator or Associate Investigator on the grant. How can I become part of the Network?

To become part of the Network, send an email to the National Project Officer (melanie.harris@rgh.sa.gov.au) or register for the Sleep Trials Network Open Forum at the Perth ASA meeting (see page 1). You will then receive newsletters and updates about educational meetings, and opportunities for initiating or collaborating on Network studies.

I want to get involved in clinical trials in sleep health but I'm not an experienced researcher. How can the Sleep Trials Network help me?

An important aim of the Network is to foster and support new researchers by providing educational meetings, consultations with experts and experience of being a collaborator in clinical trials. Get involved by sending an email to the National Project Officer (melanie.harris@rgh.sa.gov.au) or registering for the Sleep Trials Network Open Forum at the Perth ASA meeting (see page 1).

My research is not in the area of respiratory sleep disorders. Can the Sleep Trials Network help researchers like me to set up multicentre experiments?

The scope of the Network covers the full range of sleep disorders in all age groups, including insomnia, circadian disturbances, neurological disorders and sleep breathing disorders. The Network aims to support researchers planning clinical trials in all aspects of sleep health.

**BIostatISTICS & HEALTH
ECONOMICS SERVICES**

The Sleep Trials Network is currently seeking expressions of interest from consultant biostatisticians and health economists. These consultancies will provide important input, so that researchers who are linked to the Network can develop competitive research protocols for submission to grant-funding bodies.

Consultant biostatisticians and health economists can find out more about these consultancies by contacting Melanie Harris (melanie.harris@rgh.sa.gov.au).

**OBSTRUCTIVE SLEEP APNEA &
CARDIOVASCULAR EVENTS TRIAL**

The Sleep Trials Network has a great opportunity for capacity building through links with a separately funded overseas trial planned by Chief Investigator Doug McEvoy. Doug has obtained external funding and is collaborating with other Australian sleep investigators plus cardiovascular trials specialists at the George Institute of International Health (University of Sydney) to begin work in China towards a randomised trial of continuous positive airway pressure in secondary prevention of cardiovascular events in people with obstructive sleep apnea and high cardiovascular risk. Further grant funding will be sought to support a large-scale trial. By creating links with this project, the Network could gain invaluable experience in trial design, management of multi-site trials, and electronic data collection and management.

**THE AUSTRALASIAN SLEEP TRIALS NETWORK IS FUNDED BY
AN NHMRC ENABLING GRANT**

For further information or to be added to the mailing list contact:

Melanie Harris, National Project Officer

(08) 8275 1952

melanie.harris@rgh.sa.gov.au