



**IMPACT Network Report 2005/2006**  
*(Interdisciplinary Maternal Perinatal Australasian  
Clinical Trials Network)*

**IMPACT Committee 2005/2006**

The IMPACT Committee members for 2005/2006 were as follows:

Steve Cole – Obstetrics (Chair), Carmel Collins – Neonatal Nursing, Liz Davis – Consumer; Naomi Henshall – Midwifery; Carl Kuschel – Neonatology; Philippa Middleton – Other Perinatal; Roger Smith – Basic Science; Vicki Flenady – Communications Officer

**Committee elections April 2006 ANNUAL GENERAL MEETING**

Elections for four IMPACT Committee positions will be conducted at the AGM March 2006. A call for nominations for the following positions has been conducted through the PSANZ newsletter for the following positions: Obstetrics; Midwifery; Consumer.

**Impact Membership**

There are currently 230 members of the IMPACT Network.

**IMPACT Workshops 2005**

**12<sup>th</sup> March 2005 at the Women's and Children's Hospital, Adelaide**

This meeting was well attended. The main workshop themes were: *Planning Perinatal Clinical Trials: What are the urgent perinatal problems to be addressed and what outcomes are important? Trials and Tribulations: Lessons learnt in conducting perinatal trials; Increasing collaboration in perinatal trials: what works?*. The presenters were: Lex Doyle, Jonathan Morris, Roger Smith, Chris Wilkinson, Jane Alsweiler, William Tarnow-Mordi and Lesley McCowan.

• **Annual General Meeting**

During the Workshop the IMPACT Annual General Meeting was held. The election of IMPACT Committee positions was carried out. New Members elected at the AGM unopposed were: Carmel Collins – Neonatal Nursing; Philippa Middleton - Other Perinatal; Roger Smith– Basic Science; Carl Kuschel – Neonatology. Vicki Flenady agreed to stay on the Committee as the Communications Officer assisting with Newsletters, Workshops, etc. The committee elected Steve Cole as Chair and Liz Davis as Deputy Chair. Caroline Crowther has been invited on the IMPACT Network Committee representing WOMBAT.

• **Cochrane Work-In:**

IMPACT sponsored a Cochrane Work-In which was held on Sunday, 13 March 2005, following the IMPACT Workshop.

• **IMPACT Website Update:**

IMPACT Network website has been updated. Please go to <http://www.psanzpnmsig.org/impact/> to access the website – feedback is welcome

• **Australian Clinical Trials Registry (ACTR) and the IMPACT Perinatal Trials Registry (PTR)**

The ACTR has been established at the NHMRC Clinical Trials Centre as a National Register for clinical trials. All trials previously registered in the PTR will be automatically registered on the ACTR. For further information go to: [www.actr.org.au](http://www.actr.org.au) or email: [info@actr.org.au](mailto:info@actr.org.au).

**2006 IMPACT Perinatal Trials Registry (PTR) Report**  
**Compiled by Sue Jenkins-Manning, IMPACT Perinatal Trials Liaison Office and Vicki Flenady,**  
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**Brisbane, Qld.**

**NHMRC enabling grant application**

The NHMRC Clinical Trials Centre, Sydney lead by Professor John Simes submitted an application for an enabling grant with the NHMRC to develop and maintain a comprehensive national register of clinical trials with each trial being allocated a unique registration number.

This was successful and the NHMRC Clinical Trials Centre has now developed the Australian Clinical Trials Registry (ACTR), a comprehensive national register of clinical trials.

ACTR website: [www.actr.org.au](http://www.actr.org.au)

**Trials registered on PTR**

83 trials registered as at 3 March 2006. All trials currently registered on the IMPACT PTR will now be transferred onto the ACTR website. Investigators for all the perinatal trials on the PTR have been contacted by the ACTR, however the ACTR are waiting on approximately 20 responses in order to transfer these trials to the ACTR website.

**Submission of a clinical trial for publication in a ICMJE Journal**

ICMJE journals will consider trials beginning on or after July 1, 2005 only if registration occurred before the first patient was enrolled ("prospective registration").

ICMJE journals will accept "retrospective registration" of trials that began before July 1, 2005 (retrospective meaning registration occurs after patient enrolment begins). ICMJE journals considers trials that began enrolment before July 1, 2005 to be "ongoing" if the investigators were still collecting, cleaning, or analysing data as of July 1, 2005. Ongoing trials require registration before submission to a journal.

**What is the ICMJE definition of a clinical trial?**

The ICMJE defines clinical trial as any research project that prospectively assigns human subjects to intervention and concurrent comparison/control groups to study the cause-and-effect relationship between a medical intervention and a health outcome.

Medical interventions include any intervention used to modify a health outcome. This definition includes drugs, surgical procedures, devices, behavioural treatments, process of care changes, and the like.

Research projects do not require registration if their primary goal is to assess major unknown toxicity or determine pharmacokinetics (phase 1 trials). In contrast, the ICMJE editors think the public deserves to know about trials that could shape the body of evidence about clinical effectiveness or adverse effects. Therefore, the ICMJE editors require registration of all trials whose primary purpose is to affect clinical practice (phase 3 trials). Between these two extremes are some clinical trials whose pre-specified goal is to investigate the biology of disease or to provide preliminary data. However, if trials in this "gray zone" prospectively assign human subjects to an intervention and a concurrent comparison group and collect data on health outcomes (including outcomes such as adverse events), investigators should err on the side of registration if they plan to submit the study to an ICMJE journal.

The ICMJE has reviewed the ACTR registry and has determined that the ACTR meets its requirements as an acceptable registry.