

**CHILDREN, YOUTH & WOMEN'S HEALTH SERVICE
(CYWHS)**

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

REGISTERING OF CLINICAL TRIALS

The CYWHS Research Ethics Committee (REC) and Drug and Therapeutics Committee Clinical Trials Group (DTC) would like to draw researcher's attention to a joint editorial issued by members of the International Committee of Medical Journal Editors (ICMJE) which appeared in *The New England Journal of Medicine* June 9, 2005. ICMJE members stated that,

In September 2004, the members of the International Committee of Medical Journal Editors (ICMJE) published a joint editorial aimed at promoting registration of all clinical trials. We stated that we will consider a trial for publication only if it has been registered before the enrolment of the first patient. This policy applies to trials that start recruiting on or after July 1, 2005.

For further information regarding the registering of trials researchers are directed to the above mentioned editorial – <http://content.nejm.org/cgi/reprint/352/23/2436.pdf>

In Australia, the National Health Medical Research Committee has set up the Australian Clinical Trials Registry (ACTR) which researchers can access. It is a national online register of clinical trials being undertaken in Australia. The ACTR includes trials from the full spectrum of therapeutic areas. It has nationwide coverage of all clinical trials involving Australian researchers or Australian participants. General information on the registry can be found at <http://www.actr.org.au>

Any project that prospectively assigns human participants to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome ([ICMJE definition](#)) should be registered, including

early phase uncontrolled trials (phase I) in patients or healthy volunteers ([WHO Recommendation](#)). If in doubt, registration is recommended. The REC is unable to register clinical trials. Consequently, those researchers seeking to register their trials will need to do so themselves.

Please bring this notice to the attention of all researchers and potential researchers in your department.

Trials should be registered before enrolment of the first patient.

Newsletter Issue 2, Dec 2006 for the Registry may be accessed at <http://actr.org.au/docs/ACTRNewsletterIssue221Dec06.pdf>