Editorial

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Clinical Trial Registration – Now required

n May 15, 2007, BIREME published a recommendation on the Registry of Clinical Trials for the editors of journals indexed in the LILACS and SciELO databases. Since a clinical trial is an investigation that assesses therapeutic and preventive health issues, and recruits research subjects to study the possible cause/effect relationships between an intervention and a clinical outcome, registry in public databases has been proposed for ethical reasons, as a way of preserving the interests of those who participate as subjects in medical research, and also as a way of contributing to disseminating scientific knowledge applied to clinical situations.

Registry became a requirement as of September 2004, when a group of representatives from 11 medical journals of international prestige (International Committee of Medical Journal Editors - ICMJE) put out a declaration stating that their journals would now require registration as a condition for the publication of a clinical trial. Registration would have to be made in a public, easily accessible and free electronic database.

The objective was to make the existence of any clinical trial public, irrespective of its results being positive, negative or inconclusive. By 2005, this registration procedure was also undersigned by the World Association of Medical Editors.

In May 2006, the WHO (World Health Organization) announced its new standards for registration of medical research on human beings, and requested that all research institutes register studies that test therapies on humans, whether patients or healthy volunteers. According to the WHO, randomized controlled trials and clinical trials must be notified and registered before they are initiated. This will allow the identification of all clinical trials underway as well as their results, considering that not all of the trials are published as articles in scientific journals.

Note that the WHO adopts the following definition for a clinical trial: "A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc."

The websites available for the primary registration of clinical trials are: www.clinicaltrials.gov, www.actr.org.au, www.ISRCTN.org, www.trialregister.nl and www.umin.ac.jp/ctr/index/htm.

Do not fail to register your clinical trial. The Brazilian Oral Research (BOR) already requires this procedure as a condition for the publication of this type of study in the journal.

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At this time, we regret to inform you that Professor Roberto Fraga Moreira Lotufo died in São Paulo on May 8, 2008. Professor Lotufo was an Assistant Editor of the BOR, and collaborated as an *ad hoc* reviewer for over 10 years. His career achievements included President of the SOBRAPE (Brazilian Society of Periodontology) and a professor at FOUSP (School of Dentistry, University of São Paulo). He also published a great number of scientific papers in his field and left a significant contribution to the development of dental research and dental teaching in our country.