PRESS RELEASE

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Medical editors explain their requirements for mandatory registration of clinical trials

ZAGREB – Clinical trials should better be registered properly, or they will have no place on the pages of important medical journals, an international group of editors warns.

As July 1, the proposed deadline for mandatory registration of all clinical trials approaches, International Committee of Medical Journal Editors (ICMJE) issued a statement which clarifies the requirements for the registration of clinical trials in publicly available databases. The editors embraced the minimal data set of 20 items, which they identified together with other members of the World Health Organization (WHO) advisory group, and promised to consider for publication only those clinical trials which provide meaningful information for all items of the data set.

The ICMJE initiative for registering clinical trials was first put forward in September 2004. Its purpose was to promote the public good by ensuring that everyone can find key information about every clinical trial whose principal aim is to shape medical decision-making. The editors consider it a fitting way to thank the thousands of patients who place themselves at risk by volunteering for clinical trials. And the editors are not alone in pursuing this goal. The WHO works to establish a single world-wide standard for the information that trial authors

must disclose, and state governments are beginning to legislate mandatory disclosure of all trials.

Medical journal editors, on their part, announced a new editorial policy which requires of the authors to register their trials before the enrollment of the first patient. This policy applies to trials that start recruiting on or after July 1, 2005. Now authors and sponsors want to be sure that they understand the requirements. The ICMJE therefore issued a new joint statement to answer questions about its initiative and to bring its position into harmony with that of others who are working toward the same end.

In the new statement, published simultaneously in all journal members of the ICMJE, including the *Croatian Medical Journal*, the minimal registration data set is presented, and definition of a clinical trial is described in more detail. The statement explains which trials need to be registered, and what the proper way to do it is. The editors end their statement with a decisive appeal: "Every trial participant and every investigator should be asking, 'Is this clinical trial fully registered?'"

The statement was signed by the following ICMJE members: Catherine D. De Angelis (*JAMA*), Jeffrey M. Drazen (*New England Journal of Medicine*), Frank A. Frizelle (*The New Zealand Medical Journal*), Charlotte Haug (*Norwegian Medical Journal*), John Hoey (*CMAJ*), Richard Horton (*The Lancet*), Sheldon Kotzin (MEDLINE, National Library of Medicine), Christine Laine (*Annals of Internal Medicine*), Ana Marušić (*Croatian Medical Journal*), A. John P.M. Overbeke (*Dutch Journal of Medicine*), Torben V. Schroeder (*Journal of the Danish Medical Association*), Harold C. Sox (*Annals of Internal Medicine*), and Martin B. Van Der Weyden (*The Medical Journal of Australia*).

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