

Consensus Statement on Mandatory Registration of Clinical Trials

The member journals of the Surgery Journal Editors Group (SJEG), in keeping with their commitment to high ethical standards and integrity in surgical publishing and surgical science, agree to adopt the position of the International Committee of Medical Journal Editors (ICMJE)^{1,2} requiring mandatory registration of all clinical trials, whether publicly-funded or commercially-sponsored, as a condition of consideration for publication. Additionally, the SJEG will require registration of Phase I and Phase II trials.

Specifically, the SJEG supports the idea of promoting a publicly accessible clinical trial database as suggested by the World Health Organization (WHO) International Clinical Trials Registry Platform established in August 2005, which specifies 20 key

study data reporting requirements². The goal of the WHO initiative and this SJEG requirement, based on the ICMJE statement, is to promote transparency and honesty in reporting prospective clinical trial conduct and results (including negative results), to foster public trust, and to ensure that researchers behave in an ethically responsible manner toward patients and study participants.³

The SJEG member journals will require all clinical trials that prospectively assign human subjects to medical interventions, comparison groups, or control groups for the purpose of examining the potential health effects of such interventions, to be registered in one of several free, publicly accessible, non-profit electronically searchable databases such as the one administered by the National Library of Medicine

This statement is being simultaneously published in the respective journals of the members of the Surgery Journal Editors Group, as follows:

American Journal of Surgery

Annals of Surgery

Annals of Surgical Oncology

Annals of Thoracic Surgery

British Journal of Surgery

Canadian Journal of Surgery

Digestive Surgery

Diseases of the Colon and Rectum

Journal of the American College of Surgeons

Journal of Burn Care and Research

Journal of Gastrointestinal Surgery

Journal of Laparoendoscopic & Advanced

Surgical Techniques

Journal of Pediatric Surgery

Journal of Pelvic Medicine and Surgery

Journal of Plastic & Reconstructive Surgery

Journal of Surgical Education

Journal of Surgical Research

Journal of Thoracic & Cardiovascular Surgery

Journal of Trauma

Journal of Vascular Surgery

Pediatric Surgery International

Surgery

Surgery for Obesity & Related Diseases

Surgical Endoscopy

Surgical Innovation

Surgical Laparoscopy, Endoscopy

World Journal of Surgery

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(NLM), which is located at <http://www.clinicaltrials.gov>. The ICMJE defines medical interventions as those that include, among other things, drugs, surgical procedures, devices, behavioral treatments, and process-of-care changes.²

The required minimal registration data set includes a unique trial number established by the registry, funding source(s), primary researcher and public contact person, ethics committee approval, trial recruitment information, interventions and research hypotheses, and basic methodology.^{2,4}

The SJEG member journals will require registration of all prospective clinical trials as of July 1, 2007. Trials that begin after July 1, 2007 must register before enrollment of the first study subject, and trials that began before the deadline must register prior to editorial review. Submitted manuscripts must include the unique registration number in the abstract as evidence of registration.

Authors submitting manuscripts reporting on unregistered clinical trials may request consideration of their papers if they can provide sufficient evidence

of merit, although we anticipate that all clinical trials will be registered after July 1, 2007.

REFERENCES

1. Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors. *New England Journal of Medicine*. September 16, 2004; 351(12):1250–1251. <http://www.content.nejm.org/cgi/content/full/NEJMe048225>.
2. Obligation to Register Clinical Trials. International Committee of Medical Journal Editors Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. Updated February 2006, section III. J., http://www.icmje.org/#clin_trials.
3. Mandelbaum-Schmid, Judith. The World Health Organization announces new standards for registration of all human medical research. *WHO News Releases*. 2006, <http://www.who.int/mediacentre/news/releases/2006/pr25/en/index.html>.
4. Chan, An-Wen. Global opportunities and challenges for trial registration: Update from the WHO Registry Platform. WHO Geneva, October 2006, http://www.who.int/ictrp/Cochrane_plenary_26Oct06.pdf.

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