Based on recent reports, there are increasing concerns about the control of the scientific data obtained from clinical trials sponsored by industry. Many of the problems encountered are the result of restrictions contained in the research contracts that participating investigators are asked to sign. A number of solutions have been suggested to ensure the integrity of clinical trials, including the establishment of appropriately constituted trial oversight committees, negotiating noninterference pledges from industry sponsors, and creating proactive support of investigators’ rights by organized medicine.

As surgical journal editors, we stand opposed to inappropriately restrictive contractual agreements governing company-sponsored clinical trials of devices or drugs, such as those containing clauses that deny the investigators proper control over the scientific aspects of the trial or restrict access to the data and its timely publication. We believe that responsibility for the scientific data from clinical trials and its analysis, interpretation, and publication should rest in the hands of the investigators. In multicenter trials, a duly appointed and properly constituted publications committee can and usually should carry out these responsibilities.

Recently, the editors of 13 medical journals also published their opposition to inappropriately restrictive research contracts, insisting that investigators be given and assume adequate responsibility for the conduct of a clinical trial, have sufficient access to the data to perform the necessary analyses, and have control over the decision to publish. The editors further stated that they will “routinely require authors to disclose details of their own and the sponsor’s role in the study” and “...will ask the responsible author to sign a statement indicating that he or she accepts full responsibility for the conduct of the trial, had access to the data, and controlled the decision to publish” and “... will not review or publish articles based on studies that are conducted under conditions that allow the sponsor to have sole control of the data or to withhold publication.”

Editors may choose not to publish an article if the sponsor had control over the trial design, data analysis, and/or publication. These requirements for publication ethics were adopted as policy on May 11, 2001, and will be included in the next publication of the “Uniform Requirements for Manuscripts Submitted to Biomedical Journals”—a document to which we are all signatories. The revised section on “Potential Conflicts of Interest Related to Project Support” is quoted here.

Increasingly, biomedical studies receive funding from commercial firms, private foundations, and government. The conditions of this funding have the potential to bias and otherwise discredit the research.

Scientists have an ethical obligation to submit creditable research results for publication. As the persons directly responsible for their work, researchers therefore should not enter into agreements that interfere with their access to the data or their ability to analyze the data independently, to prepare manuscripts, and to publish them. Authors should describe the role of the study sponsor(s), if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the report for publication. If the supporting source had no such involvement, the authors should so state. Biases potentially introduced when sponsors are directly involved in research are analogous to methodological biases of other sorts; some journals therefore choose to include information...
about the sponsor's involvement in the methods section of the published paper.

If a study is funded by an agency with a proprietary or financial interest in the outcome, editors may ask authors to sign a statement such as, "I had full access to all of the data in this study and take complete responsibility for the integrity of the data and the accuracy of the data analysis." Editors should be encouraged to review copies of the protocol and/or contracts associated with project-specific studies before accepting such studies for publication. Editors may choose not to consider an article if a sponsor has asserted control over the authors' right to publish.

We, the undersigned surgical journal editors, support these revised guidelines and, as appropriate, will request authors of reports on clinical or basic research trials of devices and drugs to disclose details of the relative roles of the investigators and the sponsors in the conduct of the trial, the data collection and analysis, and preparation of the submitted manuscript. We may also ask the responsible author to sign a statement that he or she accepts full responsibility for the conduct of the trial, the validity of the data and its analysis, and the writing of the submitted manuscript.

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REFERENCES


Surgical Anatomy

The supraspinatus muscle inserts on the greater tuberosity, and the subscapularis muscle on the lesser tuberosity.