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The American Physiological Society
American Society for Biochemistry and Molecular Biology
American Society for Pharmacology and Experimental Therapeutics
American Society for Investigative Pathology
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The American Association of Immunologists
Biophysical Society
American Association of Anatomists
The Protein Society
The American Society for Bone and Mineral Research
American Society for Clinical Investigation
The Endocrine Society
The American Society of Human Genetics
Society for Developmental Biology
American Peptide Society
Association of Biomolecular Resource Facilities
Society for the Study of Reproduction
Teratology Society
Radiation Research Society
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International Society for Computational Biology
Association of American Physicians

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Federation of American Societies for Experimental Biology

---Quality Life Through Research---

January 10, 2006

Dr. David Korn
Senior Vice President
Division of Biomedical and Health Sciences Research
Association of American Medical Colleges
2450 N Street, NW
Washington, DC 20037-1126

Dear Dr. Korn:

On behalf of the Federation of American Societies for Experimental Biology (FASEB) and the more than 80,000 researchers it represents, we would like to offer our support for the Association of American Medical Colleges (AAMC) report on Integrity in Reporting of Clinical Research Studies. Your principles provide both timely and effective guidance for strengthening the clinical research enterprise and we endorse your efforts. We would also like to suggest one further addition that we believe would help to bridge the gap that exists between industry and academia on this issue.

Your principles do an outstanding job of addressing the concern that trial sponsors remain at arm's length in terms of data analysis and publication. You make the point that investigators and institutions need to take responsibility for ensuring that issues relating to "...appropriate access to trial data and unfettered rights of publication of clinical trial results..." are raised during the contracting phase. We would also encourage you to take this opportunity to delineate other areas of investigator responsibility, some of which might include maintaining confidentiality, full commitment to the percent effort agreed upon during the contracting process, acknowledgement of the limitations of personal expertise during the initial negotiation phase for the trial, and full acknowledgement of both the strengths and limitations of the study, not only in publications, but also in communication with the media.

Dr. Korn, thank you for allowing FASEB the opportunity to comment on your guidelines. As we go forward with our work on clinical research policy issues, we hope to be in close contact with AAMC.

Sincerely,

Bruce R. Bistrian, M.D.; Ph.D.
President
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Janet Hall, M.D.
Chair
FASEB Clinical Research
Subcommittee