



Federation of American Societies for Experimental Biology

— *Quality Life Through Research* —

Member Societies

The American Physiological Society
American Society for Biochemistry and
Molecular Biology
American Society for Pharmacology and
Experimental Therapeutics
American Society for Investigative
Pathology
American Society for Nutrition
The American Association of
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Teratology Society
The Endocrine Society
The American Society of Human
Genetics
Society for Gynecologic Investigation
Environmental Mutagen Society
International Society for
Computational Biology
American College of Sports Medicine
Biomedical Engineering Society

January 28, 2009

Michael A. Carome, M.D., Captain
U.S. Public Health Service
Office for Human Research Protections
1101 Wootton Parkway
Suite 200
Rockville, M.D. 20852

BY ELECTRONIC MAIL TO: discontinueparticipation@hhs.gov

Re: Guidance on Discontinuation of Subject Participation

Dear Dr. Carome:

On behalf of the Federation of American Societies for Experimental Biology (FASEB), I am writing to express our appreciation for the Office for Human Research Protections' *Draft Guidance on Important Considerations for When Participation of Human Subjects Research is Discontinued*. As an organization representing 22 biomedical research societies and over 80,000 basic and clinical investigators, FASEB recognizes the importance of protecting research participants and the clinical data they provide. At the same time, we know it can be challenging for investigators to determine whether or not they can continue to collect, use, and analyze data from research subjects after their participation in a study has been completely or partially terminated. These guidelines clarify the federal regulations on this matter and provide a useful case study to help researchers and institutional review board officials apply the regulations to specific research projects.

We thank you for the opportunity to comment on this draft guidance and look forward to the final document when it is released. In the meantime, please do not hesitate to contact me if FASEB can be of assistance to you on this or other issues related to the protection of human research participants.

Sincerely,

Richard B. Marchase, Ph.D.
FASEB President

President

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