



June 30, 1998

Harold Varmus, MD
Director
National Institutes of Health
Bldg. #1, Room 126
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Varmus:

A solution is beginning to emerge to the very vexing problem of how to allocate the cost of animal care on federal grants. Your support and intervention is needed to ensure that this proposed solution -- which is gaining support from scientists and the research institutions -- receives a thorough and informed hearing at the Office of Management and Budget (OMB).

Controversy has blocked a revised Cost Analysis and Rate Setting Manual for Animal Research Facilities (CARS Manual). The NIH's National Center for Research Resources asked the National Research Council (NRC) to study the issue. The NRC's Committee on Cost of and Payment for Animal Research recently released its interim report.

"Approaches to Cost Recovery for Animal Research: Implications for Science, Animals, Research Competitiveness, and Regulatory Compliance" is an impressive document. Rather than reflecting a simple compromise among the committee members' initially quite disparate views, this report situates the issue in the broader scientific and regulatory context, and develops its own incisive analysis.

The report chronicles the development of centralized animal facilities, and it explains how they provide

the high quality animal care on which cutting edge biomedical research depends. The report finds that "the ARF is now an integral part of the research program." Further, the report clearly explains the implication of this evolution in animal-based research: "The space used to breed, rear, exercise, and house animals according to their behavioral needs during the conduct of research is an integral part of an individual investigator's research space." In the end, the report translates these developments in scientific practice into the language of cost recovery:

The space in an animal facility is used to conduct research, as is space in any research laboratory. The cost of other laboratory space is included in the F&A cost pool, so it would be inconsistent to treat the cost of ARF space as direct costs in per diem rates.

I understand that, at this point, the CARS committee is ready to move forward with a rate-setting manual that would reflect the findings of the National Research Council panel. However, action on the new manual is stayed, pending clarification of OMB's position. In recent years, OMB has viewed animal research facilities as specialized facilities under A-21, an interpretation that would require that all costs associated with the facilities be treated as direct costs and that all of these costs be loaded into per diems. The NRC report clearly rejects that interpretation, and the report spells out the ways in which implementing that interpretation would compromise animal welfare and research progress.

It is our understanding that OMB is reviewing its A-21 interpretation in light of this NRC report, and that this review will involve consulting with the Department of Health and Human Services.

I would ask your assistance in breaking the logjam surrounding the CARS Manual, and in supporting the NRC panel's consensus so that we can resolve the controversy that has been so frustrating to researchers, institutions, and funding agencies, and so that biomedical research using animal models can proceed unimpeded. Specifically, I would ask that you communicate with Secretary Shalala regarding this issue, informing her that implementing the National Research Council recommendations will advance research progress.

Thank you for your efforts. Please contact me if I can be of assistance on this matter.

Sincerely,

Ralph G. Yount, PhD
President

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