

FASEB Representatives to Participate in NIH Review of Regulatory Burdens on Federally Funded Research (October 1998)

FASEB has been asked to provide expertise and guidance for a congressionally mandated study of ways to decrease regulatory burden on NIH-funded research. FASEB's public affairs committees recommended more than two dozen members of FASEB societies to represent the views of working bench scientists in focus groups convened as part of the review.

The NIH study will examine five areas of research regulations: animal welfare, human subject protections, scientific misconduct, conflict of interest, and hazardous waste disposal. The purpose of the focus groups will be to identify targets of opportunity for reducing regulatory burden and to propose specific solutions.

Several of the FASEB-recommended researchers will be serving as advisors to the study. They include Robert Rich, MD, (Scientific Misconduct); David Kaufman, MD, PhD, (Scientific Misconduct), and Joseph R. Haywood, PhD, (Animal Welfare).

The specific regulations to be considered by each group will be as follows:

Animal Welfare: Policies of the Public Health Service (PHS) which require institutions to follow particular procedures, including Institutional Animal Care and Use Committees, to ensure the appropriate care and use of research animals. This group will consider the impact that some of the USDA regulations have on researchers.

Human Subject Protections: Regulations designed to protect participants in federally sponsored research, including Institutional Review Boards. This group will review only programs of the NIH's Office of Protections from Research Risks and not those of the Food and Drug Administration.

Scientific Misconduct: Regulations which require entities receiving grants or cooperative agreements from the PHS to have uniform policies and procedures for investigating and reporting instances of alleged or apparent misconduct involving research, research training, applications for these activities or related activities supported with PHS funds.

Conflict of Interest: Regulations which establish procedures that ensure that the design, conduct, or reporting of research funded by the PHS will not be biased by any conflicting financial interest of investigators responsible for the research.

Hazardous Waste Disposal: Regulations which set standards governing the management and disposal of hazardous wastes. While the regulations of other levels of government may complicate this issue, this group will only review federal regulations.