



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
Office of the Director



Office of Extramural Research
Building 1 Room 144
Bethesda, Maryland 20892
(301) 496-1096
(301) 402-3469 - FAX
<http://grants.nih.gov/grants/>

JUL 02 2009

Michael A. Budkie, A.H.T.
Executive Director, S.A.E.N.
1081 B St., Rt. 28, PMB 280
Milford, Ohio 45150

Dear Mr. Budkie:

On behalf of the National Institutes of Health (NIH), I am providing some additional information regarding your June 1, 2009 letter to Secretary Vilsack, Dr. Gibbens and Dr. Goldentyer of the United States Department of Agriculture (USDA).

As the nation's principal health research agency, the NIH conducts and supports research in pursuit of knowledge to reduce the burden of disease and disability for all Americans. The National Eye Institute (NEI) provides support to clinical and laboratory research on visual development, neural processing, eye movement and other disorders involving output of the retina and other portions of the brain that serve vision. Knowledge of the normal visual system provides a foundation for understanding the causes of impaired vision and developing corrective measures. Researchers have acquired new details about the neural mechanisms that control the initiation, direction, and duration of eye movements, including the brainstem mechanisms responsible for saccadic eye movement and the cortical mechanisms responsible for control of gaze. Progress is being made in understanding the relationship between eye movements and the posture or movement of the limbs and head. Taken together, this research has and continues to provide pivotal information for developing new interventions and treatments for eye diseases and blindness.

In your letter, you describe a process developed by your organization and applied to research supported by NEI. Using this process you found over 50 grants to be duplicative. The process, however, appears to focus only on research methods, not on the question being addressed by the research. Many research methods are used repeatedly by scientists to help ensure that answers to questions are based on true biological and behavioral reasons and not due to spurious effects related to differences in methodology. What is critical is that the questions being asked are not duplicative across the research projects. By taking into account the research questions being addressed, one will find that the 50+ grants that you listed are not duplicative. The investigators are examining many different visual areas in the brain with means of analysis, questions, and outcomes that are unique to each funded project and taken in their entirety, constitute a strong contingent of projects to advance science and accumulate knowledge.

Equally important to note is that if animals are to be used, NIH policy requires that applicants provide justifications for the use of animals, choice of species and numbers to be used along with a description of procedures for minimizing any discomfort, distress, pain or injury that may result from the proposed research. Members of scientific review groups (i.e., study sections) evaluate the applications to determine if the proposed research has high potential for scientific advancement and if plans for the use of animals

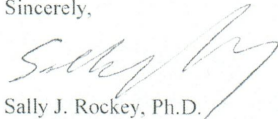
are justified and appropriate relative to the scientific work proposed. Because NIH receives more requests for support than we have funds, only the most meritorious grant applications are chosen for funding

As you know the use of animals in NIH-supported biomedical research is highly regulated at both Federal and institutional levels. The USDA implements the Animal Welfare Act and its regulations and policies, while the NIH Office of Laboratory Animal Welfare (OLAW) is responsible for carrying out the provisions of the Health Research Extension Act. Because of these laws, both the USDA and the NIH OLAW have oversight authority with regard to the use of animals in NIH-supported research. As mandated by the laws, a researcher who needs to use animals as a part of their research must submit a discussion of the experiments and a scientific justification of the need for the use of animals in those experiments to their local Institutional Animal Care and Use Committee (IACUC). The IACUC must look at the appropriateness of the species, the number of animals requested and consideration of alternatives to the use of animals if this research will result in pain or distress. The researcher must also describe how the pain or distress will be alleviated or minimized. The IACUC carefully considers the request for the use of animals in the proposed research, and if the IACUC finds a problem, it calls its concerns to the attention of the researcher. The committee does not approve the research until its concerns are resolved. Moreover, the NIH will not fund the research until the IACUC has reviewed and approved the request to use animals.

In conclusion, the peer review system in conjunction with the oversight provided by OLAW provide a rigorous set of checks and balances to assure that animals used in NIH research are scientifically justified and that their care and welfare is respected and thoroughly considered. A significant element in both the scientific justification and welfare considerations is that the research question is not redundant, but rather advances science and knowledge.

I hope this information helps to clarify NIH procedures and, together with the information provided by USDA, helps to provide a fuller description of the role of each agency in assuring the welfare of animals used in research.

Sincerely,



Sally J. Rockey, Ph.D.
NIH Acting Deputy Director for
Extramural Research