Dr. Lyric Jorgensen
Office of Science Policy
Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

December 1, 2010

Dear Dr. Jorgensen,

Statement by Comparative Medicine Institutional Training Grant Directors to the National Institutes of Health Scientific Management Review Board

The directors of the 45 veterinary institutional training grants supported by the National Center for Research Resources (NCRR) submit the following comments to the Translational Medicine and Therapeutics (TMAT) working group and the NIH Scientific Management Review Board (SMRB).

We would like to emphasize the value of the NCRR, and in particular the institutional training grants currently administered by the Division of Comparative Medicine (DCM), to the success of biomedical research and translational medicine. These grants address an important infrastructure need for biomedical research by providing high-quality, mentored training in comparative medical research for veterinarians. Regardless of the organizational fate of the NCRR, the "training pipeline" it provides is a critical element of our national research infrastructure and should not be lost or diverted.

Comparative medical veterinary scientists are uniquely positioned to understand and explore the interspecies comparisons that are an essential element of translational research. They are an indispensible component of the scientific workforce as both independent and collaborative investigators, with the knowledge and training required to avoid misinterpretation of experimental findings in animal model systems. The need for such qualified individuals is outlined in the National Research Council's publication *National Need and Priorities for Veterinarians in Biomedical Research* (National Academy Press, 2004).

The vital contribution of comparative medical veterinary researchers to the development of therapeutic agents is most evident in those studies requiring use of the Food and Drug Administration's Animal Rule, which governs the development of new drug and biological drug products when human efficacy studies are not ethical or feasible. The rule requires (1) "a well-understood pathophysiological mechanism", (2) "a sufficiently well-characterized animal model", (3) a study endpoint "clearly related to the desired benefit in humans", (4) "[understanding of] pharmacokinetics and pharmacodynamics [sufficient to expect] effectiveness in humans" (FDA, Federal Register 2002, 67:37988-98). Any meaningful degree of validity in the assessment of these criteria requires the expertise of veterinarians trained in research.

We believe that the training provided for comparative medical veterinary scientists should be supported by a non-categorical mechanism, because the nature of the skills provided by our training programs exceeds the purview of any specific categorical NIH institute. While some graduates of our programs have gone on to specialize in a field supported by a specific institute, most work collaboratively across multiple organ systems or disease entities.

The Division of Comparative Medicine has served translational medicine well to date, and is poised to flourish in the context of the new Center for Translational Science proposed by the TMAT working group. The program directors and administrators have the extensive experience and insight necessary to bring the capabilities of veterinary and comparative scientists to bear in the service of human health needs.

We therefore recommend:
1. That individuals with appropriate comparative medical expertise be involved in the development of the reorganization plan for the future of NCRR programs

and

2. That the Division of Comparative Medicine and the programs it oversees be maintained as is or become fully incorporated as an entire unit in future configurations of the NIH.

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