DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Heart, Lung, and
Blood Institute
Bethesda, Maryland 20892

July 13, 2020

Nathan Herschler, Executive Director
New England Anti-Vivisection Society(NEAVS)
333 Washington St Suite 850
Boston,MA 02108

Dear Mr. Herschler:

Thank you for your June 25, 2020, letter to Dr. Gary Gibbons, Director of the National Heart, Lung, and Blood Institute (NHLBI) regarding project grant 1R01HL139673-01 at Virginia Commonwealth University. As Director of the NHLBI's Division of Lung Diseases, which administers this grant, I am pleased to respond on Dr. Gibbons' behalf. The project, "High Efficiency Delivery of Surfactant Aerosols to Infants without Intubation," aims to test a novel way of administering surfactant to premature babies without the need for an endotracheal tube, using a special powdered aerosol of the synthetic surfactant. The use of surfactant, based on science funded by the NIH, has dramatically increased survival of babies born prematurely who lack this vital substance to keep their lungs open after birth.

The mission of the National Institutes of Health (NIH), of which NHLBI is a part, is to seek fundamental knowledge about the nature and behavior of living systems and application of that knowledge to enhance human health. To study health and disease, NIH-supported scientists use a wide variety of research approaches, including animal models, human subjects, cultured cells, computer modeling, and methods in biochemistry, molecular biology, and engineering. Each approach and technology provides unique contributions to understanding the complexities and spectra of diseases that affect human health, including respiratory distress.

All grant applications submitted to the NHLBI proceed through a rigorous two-step review process. The first level of review is conducted by a Scientific Review Group composed primarily of non-federal scientists with relevant expertise. The second level of review is conducted by the NHLBI Advisory Council, which consists of scientific experts and public representatives. Each level of review takes into account the scientific merit of the proposed research, its potential impact on public health, and its alignment with the NHLBI mission.

The review process also covers proposed research models and methods. Grant applicants who plan to use animals in their research are required to justify the need for animals, select the most appropriate species, explain why the research cannot be accomplished without an alternative model, and use the fewest number of animals possible. They are also required to minimize animals' exposure to pain, distress, and discomfort "to that which is unavoidable in the conduct of scientifically valuable research.

These rules are enforced by Institutional Animal Care and Use Committees (IACUCs) at every NIH-funded institution. IACUCs review animal research projects from the planning stage through completion. All IACUCs include at least one veterinarian and one community representative who is unaffiliated with the institution. They are required to conduct regular inspections of animal research facilities and to investigate complaints, and they are authorized to stop any project that fails to meet federal standards. The Office of Laboratory Animal Welfare requires institutions to use the National Research Council's 8th edition of *Guide for the Care and Use of Laboratory Animals* https://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth as the basis for their program of animal care and use.

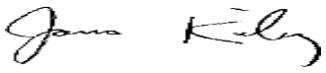
The research proposed in this grant aims to apply principles of physics to design a system for aerosol delivery of surfactant, prepared in such a way as to help delivery of the medication down the airways of the lung to reach the tiniest, most distal airways where it is most needed, in a spontaneously breathing baby, without need for placing an endotracheal tube. The experiments proposed include studies of physics and flow, studies in rat models to demonstrate that such delivery is possible, and in the final aim, testing the delivery method in ferrets, which have lungs similar to those of a premature baby, both in the size of the airways and the number of branches. This will help determine how surfactant can be safely administered in premature newborns without needing to invasively intubate them for the delivery of surfactant.

This application underwent rigorous review prior to award, which included examining the value of the science to human health, the choice of the ferret as the animal model after validation in a rat model, and the way animals are handled and treated at the facility.

As with all NIH grants, we pay close attention to this grant's progress and performance, including the ferret experiments. Compassionate use of laboratory animals is of the highest priority to the NIH, balanced with the potential benefits to science and humanity. We plan to share your concerns with the investigators of this grant to ensure the welfare of the animals in use, and to take corrective action if warranted.

We appreciate your interest in NIH-funded research and your concern regarding animal studies. We encourage you to read more about the important role of animals in research and how the NIH ensures animal welfare at https://grants.nih.gov/grants/policy/air/general_public.htm.

Sincerely,



James P. Kiley, Ph.D.
Director, Division of Lung Diseases