



April 22, 2023

Jay Bhattacharya, MD, PHD, Director National Institutes of Health (NIH) 9000 Rockville Pike Bethesda, MD 20892

Via email: nihnmb@mail.nih.gov

Dear Director Bhattacharya:

The American College of Allergy, Asthma and Immunology (ACAAI) and its Advocacy Council are writing to share our concerns about the National Institutes of Health's (NIH) grant application policy.

<u>ACAAI</u> represents more than 6,000 board-certified allergists and healthcare professionals. Allergists specialize in treating both adult and pediatric patients with chronic conditions such as asthma, food allergies, hives or urticaria, stinging insect hypersensitivity, sinus problems, allergic rhinitis, anaphylaxis, immune deficiencies, and atopic dermatitis or eczema, among other allergic diseases.

For as long as the NIH has funded research grants, allergy physicians and researchers have relied on grants from the NIH to fund life-saving medical research. For example, a NIH-funded study helped lead to the approval of an important new medication for food allergies. Another NIH-funded study helped prove that early exposure to peanuts "enabled 100% of children with peanut allergy who initially could tolerate the equivalent of at least half a peanut to consume three tablespoons of peanut butter without an allergic reaction."

Another such group is the Consortium of Eosinophilic Gastrointestinal Disease Researchers (CEGIR) - the global leader in the understanding, research, and treatment of eosinophilic gastrointestinal diseases, a set of chronic diseases of the immune system. The group has been funded by a Cooperative Agreement Grant from the NIH for the past 11 years. The grant was written over one year ago, submitted in August 2024, and underwent scientific review in November and was scheduled for final review in February 2025. However, the review was delayed until April and then May.

On April 14, CEGIR was alerted that its grant application was dismissed, due to a technicality (missing one paragraph justifying foreign components in their 1475-page application). CEGIR rapidly submitted a rebuttal to this, but it was unsuccessful. The Office of Scientific Review explained that the NIH is following a new process that invoked the requirement for this paragraph based on policies of the new administration. CEGIR has had the same foreign components for the past two cycles, and *the standard procedure has been to have the "foreign components" paragraph justified during the post-review period.* The NIH is allowing a technicality to cancel a grant for critically needed research.





CEGIR is a world leader in understanding and treating chronic diseases of eosinophilic gastrointestinal diseases in childhood. As a world leader, it has interactions with people in other countries. These interactions are not significant for the work of CEGIR. There is no research being conducted outside of the United States. CEGIR has never spent any NIH funds for these foreign associations, and the foreign associations are very much peripheral to the work of CEGIR. CEGIR is willing to remove any loose foreign components from the grant.

Unlike regular grants (e.g., NIH R01s), CEGIR cannot simply re-apply in the next cycle as the RDCRN grants are only available every 5 years. This abrupt end to CEGIR means that nearly one thousand people will suddenly stop participating in clinical studies and life-saving research will be discontinued. Based on the CEGIR grant alone, thousands and likely millions of lives are at risk because of this unfathomable action. The welfare of Americans is greatly compromised.

The CEGIR grant is focused on the topics included in the new administration's "Make America Healthy Again (MAHA)" Commission, which targets chronic childhood diseases, food and other types of allergies.

Given the above, please enact the following:

- NIH grants denied due to the Foreign Components Justification paragraph shall be reviewed again.
- The review of these grants should accept an addendum related to foreign components.
- Call upon NIH to reinstate application 3U54Al117804 and others based on the modifications above.

We appreciate your consideration of these requests. If you have questions or would like to discuss this issue further, please contact Susan Grupe, Director of Advocacy Administration.

Sincerely,

James M. Tracy, DO, FACAAI President, ACAAI

Travis A. Miller, MD, FACAAI Chair, Advocacy Council