Gillingham Lab

# RESEARCH NEWSLETTER

You may be aware of news circulating in the US regarding changes made by the current administration to the National Institutes of Health (NIH), a major source of our research grant funding. Naturally, a lot of people have asked what this means for our lab and FAOD research in general. Although we don't have all the answers, we thought an explanation of how the application, review, and awarding process of NIH grants works and what we know of the current changes being implemented may be helpful when you hear about these changes in the news.

# **HOW THE NIH GRANT PROCESS WORKS**

## **STEP 1: PLAN, WRITE & SUBMIT AN APPLICATION**

Applying for NIH funding is a highly competitive process! 80–85% of the NIH budget is used to support research outside of the NIH with the remaining 10% being used to support research within their own laboratories in Bethesda, Maryland. There are three cycles of application, review and award each year. The NIH is made up of 27 institutes and centers that each have their own focus on a specific disease, organ system or stage of life. In previous years, the success rate of an application being funded was around 11–20%.

The process of writing and submitting a grant application to NIH requires months of planning, writing, and collaboration among team members. The first step is, of course, to figure out what your research question is and how you will answer it. The research must be unique and not have been conducted previously. Collaboration amongst researchers is encouraged.

After you have established your plan, you then have to find a fit for your research within one of the NIH institutes, centers, or offices that fund the grant awards, review their funding opportunities and submission deadlines. As an example, our Natural History of LCHAD Retinopathy grant was submitted to and awarded by the National Institute of Child Health and Human Development (NICHHD) whose mission is "to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all".

The next step is to write your application. Applications for research in humans need to include what your research question is, scientific background about the research, the research plan (e.g. where it will take place, who is the population to be studied, how will they be enrolled, what are the study procedures, etc.), who will be the key researchers working on the study and their qualifications, the study budget, and plans to protect participants and their data. Once all of this information is assembled, it is submitted electronically and received by the NIH.

### **STEP 2: THE APPLICATION IS REVIEWED**

When the NIH receives the grant application, it is first assigned to a study section or panel of experts relevant to your research. Each study section is made up of about 30 volunteer, non-government scientists who have expertise in a specific research area. At least 3 members of a study section are assigned to provide an objective peer review of your application, critique it, and assign it a preliminary Overall Impact score. The application is then presented to the whole study section during a review meeting, discussed, and the whole section provides a final Overall Impact score. The Overall Impact score ranges from 10 (high impact, exceptional) to 90 (low impact, poor). The impact score and a summary statement are then released back to you, along with critiques on the strengths and weaknesses of the research, any budget recommendations, or other comments.

During the second step of review, the NIH staff members of the Advisory Council review the list of applications, the Overall Impact scores, and summary statements and make recommendations on what applications should be funded. Typically, a low score or high impact application will be recommended for funding.

## **STEP 3: FUNDING DECISION AND ACCEPTING AWARD**

The Institute/Center Director makes the final decision on whether an application should be funded. If the application is funded, you are provided with a Notice of Award and accept the award by requesting funds.

# WHAT HAS CHANGED (SO FAR) AT THE NIH

Within a grant budget, there are cost items designated as direct costs vs. indirect costs. Direct costs are expenses that can be directly tied to the specific research project, such as salaries for time spent on that project, equipment or supplies for the research study, and costs for study procedures. Indirect costs are expenses that cannot easily be assigned to one project and relate to more common/shared costs. They may also be referred to as Facilities & Administrative costs. These include expenses such as maintaining research facilities or shared resources. They cover the costs of Institutional Review Boards or IRBs.

OHSU negotiated a 56% indirect cost rate for NIH grant budgets. Effective February 2025, the NIH implemented a standard 15% cap on indirect costs. A judge blocked implementation of this cut by a nationwide temporary court order while a lawsuit is pending, and future decisions are uncertain, but a cut to indirect rates at OHSU of this size would significantly reduce the ability to maintain research spaces and resources available to us to complete our research projects.

A separate proposal to cut the NIH's budget in fiscal year 2026 by 40% and to eliminate or consolidate most of the 27 NIH institutes/centers into only 8 is currently under consideration. NIH Funding Opportunities were offline for several months, but have since reappeared, although with significantly less funding opportunities posted. As previously mentioned, the past acceptance rate of grant applications was 11–20%. If the proposed cut to the NIH budget and reduction in NIH institutes/centers takes place, this acceptance rate will drastically drop and chances of funding will be greatly reduced.

NIH grant applications previously required plans to enhance diversity in perspectives, ideas, or recruitment. These requirements have been removed and applications that have diversity components currently under review will not be evaluated or considered. The goal of increasing diversity and inclusion in human subjects' research is to increase participation of underrepresented groups and enhance our ability to make more robust and inclusive assumptions and application of research findings across the population. We still believe these are important goals.

## THE WAY FORWARD

What does this mean for us? Undoubtedly, it makes our chances of successfully obtaining NIH funding more difficult, but it doesn't mean that the work we are doing should stop. We are fortunate to also receive support from private donors. There are other grant funding agencies we can apply to for funding, and potential industry sponsors to partner with to forward our research goals. We are hopeful and will continue to try to take two steps forward for every one step back.

#### **REFERENCES**

Information on the NIH grants process and current and proposed changes were obtained from <a href="https://grants.nih.gov">https://grants.nih.gov</a> and current news reports.

# PLEASE CHECK OUT THESE OTHER RECENT UPDATES!



### **New publications:**

Patient-reported visual function outcomes agree with visual acuity and ophthalmologist-graded scoring of visual function among patients with long-chain 3-hydroxyacylcoA dehydrogenase deficiency (LCHADD)

Article link: https://doi.org/10.1016/j.ymgmr.2024.101171

D-BHB supplementation before moderate-intensity exercise suppresses lipolysis and selectively blunts exercise-induced long-chain acylcarnitine increase in pilot study of patients with long-chain fatty acid oxidation disorders

Article link: <a href="https://doi.org/10.1016/j.ymgme.2025.109070">https://doi.org/10.1016/j.ymgme.2025.109070</a>



Dr. Gillingham gave a presentation for the MitoAction Expert Series on ketones. Find the link to the recorded talk on MitoAction.org on our **Publications and Presentations** page (https://www.ohsu.edu/school-of-medicine/gillingham-lab/publications-and-presentations).