March 3, 2025

Frozen Sections: A Study in Science Stopped Cold

A letter from David A. Brenner, MD, President and CEO of Sanford Burnham Prebys

Since the end of World War II, when the federal government first determined that it would become the primary driver of American science, the National Institutes of Health, the largest funder of biomedical research in the world, has relied on a two-pronged process to fund biomedical research:

First, "study sections" would assess the quality and viability of proposed research grants.

Second, there would be a final review by an NIH advisory council and funding would be approved for worthy proposals.

After inauguration, the Trump administration initially froze all federal funding, including for biomedical research.

Top: the first NIH study section in 1946 and a study section today.

When a court issued a restraining order requiring them to backtrack, the administration decided to take an end-run around the court order. The NIH stopped the standard required practice of posting public meeting notifications in the Federal Register, the official daily publication of the U.S. government. As a result, dozens of long-scheduled study sections and advisory councils were canceled, effectively suspending the review process and stopping all new grant funding.

No notice, no meetings.

No meetings, no grants.

No grants, no science.

Study sections are gatherings of independent scientists deemed among the best and most experienced in their field(s). They possess the knowledge and expertise to effectively judge the

merits of a grant application: Is the research topic and goal worthy of investigation? Does the applying researcher possess the credentials and abilities to effectively conduct the science proposed? Is there compelling data to support the proposal? Will the money be well-spent?

Study sections are grueling. They are not for the weak of heart or data. Proposals are frequently rejected, sent back with requests for more information, more research or greater refinement. Proposals that make it to the second and final stage have been scored on a 9-point scale (from 1 for exceptional to 9 for poor) for both overall impact and individual review criteria. These proposals compete against other scored proposals for actual funding.

Only the best of the best prevail, and not very many of them. Each year, the National Institutes of Health receives more than 50,000 grant proposals, a number that is steadily increasing. *Less than one in five* of these proposals is funded, a number that is steadily decreasing.

Study sections are the engines of science. They move research from idea to action. If they aren't working, neither is science.

Study sections aren't the only part of the research machine that has stalled. Required notices of meetings by advisory councils have also largely stopped. The meetings provide additional review and make final funding recommendations.

Each of the 27 NIH institutes has its own advisory council and they typically meet in January, May and September. None of these councils has met since the communications freeze was ordered in late-January, effectively cutting off the means to award new grants.

The result: New science has effectively stopped. Researchers at institutions, large and small, who have labored for months, perhaps years, to develop new proposals cannot obtain required feedback, let alone funding. The study section halt has already held up an estimated $1.5 billion in new funding for everything from Alzheimer's disease and cancer to allergies, addiction and antibiotic-resistant bacteria.

The harm is real. Scientists who cannot get their research reviewed and funded in timely fashion face the prospect of cutting back their work, including laying off staff and support personnel. Some universities and medical schools have already enacted hiring freezes or paused graduate admissions.

The veteran scientists who participate as reviewers in study sections are usually unpaid. They do it as a service to each other and to keep science moving forward. With study sections suspended, nothing is moving, including progress toward improved health.

Sincerely,

David A. Brenner, MD
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