

## Federal Cuts Shake Up Clinical Research Funding Landscape

By **Hannah Albarazi**

*Law360 (July 29, 2025, 1:31 PM EDT)* -- For decades, clinical research depended on federal grants to nurture nascent, unproven ideas while private investment primarily went to more mature, reliable research. But after deep funding cuts by the Trump administration, healthcare attorneys worry that delicate balance is at risk.

Crowell & Moring LLP partner Linda Malek recently discussed industry concerns with the federal government's reduction in clinical research funding with Law360 Healthcare Authority, saying some fear that the United States may lose its status as "standard-bearer" for innovation and research.

Malek, who frequently advises entities in academia and the life sciences industry, also points to a dearth of predictability right now, noting that the Trump administration's executive orders have created "a moving target" for compliance.

This interview has been edited for length and clarity.

### What has clinical research funding traditionally looked like?

Traditionally, federal funding has been relied upon in the clinical research context to help answer early questions when private funders, like pharma or private equity, are not yet ready to invest.

Private funding, traditionally, comes into place when, for example, a pharma company wants to test a drug or a device. Or where you have a discovery that has often come out of academia, and that discovery becomes a company and is looking to spin out and develop further.

That becomes a target for private investment, either by the pharma industry looking to invest and bring that discovery into its portfolio or by venture capital and other private arms looking to invest. Often, the bridge between government funding and private funding are research foundations.

### What changes are you seeing in 2025, and what led to them?

The first one was in the context of government funding for indirect costs — overhead costs, costs to keep the lights on, cost to keep the lab open — as opposed to direct costs, which are costs to fund the staff that's conducting the research, for example. Those indirect costs are paid at a rate that universities negotiate with the federal government. They can sometimes be 50% or more of direct costs.



Linda Malek

What we saw fairly early in the new administration was a blanket attempt to lower those indirect costs to 15% of direct costs. So that's a very dramatic reduction.

*(Editor's note: The policy's implementation has largely been stalled in court.)*

The second thing that we started seeing were changes to attestations that need to be made by the recipient of government grants. Traditionally, these attestations are around compliance with things like Title IX and the Common Rule, which protects the rights of human subjects.

What we started seeing were changes to attestations to include compliance with executive orders that went to other types of issues that you typically would not see in a clinical research grant. So, executive orders related to DEI, gender ideology, things like that.

Having to comply with executive orders was not something that had ever been included in a certification to draw down on a federal grant.

You are having to stay compliant with what is essentially a moving target, which is a very different compliance posture than attesting to compliance with a set of regulations that cannot change unless they go through a particular process.

### **What does clinical research funding look like after these changes?**

Overall, there is reduced federal funding for clinical research, and there is less predictability with respect to being able to both draw down for new funds and/or continue with ongoing research.

There is increasing focus among stakeholders around whether there are opportunities for different kinds of private sector investment, particularly at earlier stages in the clinical research continuum.

There is a feeling that private sector money cannot fill the gap that has been created right now by the decrease in federal funding. However, I do think that all the stakeholders in this environment are talking to each other about whether there are ways to look at funding differently in order to try to fill some of the gaps.

There's a lot of concern because this is often life-saving research and the United States has been the standard-bearer for quite a long time in terms of innovation and research. It's really in no one's interest to lose that.

Hopefully, there will be additional measures coming out of the federal government that will stabilize the funding process going forward. I think that is still very much an evolving area.

I think that there is certainly an increased effort, for example, at the U.S. Food and Drug Administration to move research through at a steady pace. And that is not funding-specific, but it does show support for the idea of continued research at a pace that allows for invention and discovery to move forward and not stagnate.

### **How can stakeholders in this area adapt to these and other changes?**

To the extent that a research grant has been terminated, and an entity feels that it's been terminated

wrongfully or incorrectly, that should be appealed. That should be challenged.

Secondly, I think entities should be looking closely at their own internal compliance programs to ensure that they don't run afoul of some of these new standards for obtaining and continuing to receive federal funds, and minimize any vulnerabilities.

So, looking at their overall compliance programs as they relate to these standards will be important as well.

--Editing by Haylee Pearl.

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