Report on Research Compliance Volume 15, Number 5. May 31, 2018 Congress Halts NIH's Revised Clinical Trials Policy, But Next Steps Unclear

By Theresa Defino

Members of Congress love NIH. Each year when director Francis Collins and a few institute or center directors testify before members of appropriations committees, they are showered with praise for their mission and life-saving research. Last year, Congress gave NIH an increase of $2 billion (*RRC 4/17, p. 1*). Most recently, members denied the Trump administration's request for double-digit cuts and instead granted a $3 billion increase to $37 billion for fiscal year (FY) 2018, an 8.3% boost.

But on occasion, Congress gives NIH a bit of a scolding, as it recently did. This came in a report accompanying the FY 2018 appropriations legislation. Bowing to concerns, Congress has required NIH to pull back from its new clinical trials policy that critics said had improperly subjected some research to expanded reporting to ClincialTrials.gov, and other new requirements. The policy has been in effect since January.

After years in draft form and following several delays, the policy went into effect Jan. 25. But many found some of the requirements, including trial design and award submission, confusing and illogical (*RRC 3/18, p. 1*).

In a report accompanying H.R. 1625, which provides appropriations for the rest of this fiscal year, Congress required NIH "to delay enforcement of the new policy published in the *Federal Register* on September 21, [2016]—including NIH's more expansive interpretation of 'interventions'—in relation to fundamental research projects involving humans."

Instead, the new policy should be applied to "research projects that would have been considered clinical trials under the prior policy. This delay is intended to provide NIH sufficient time to consult with the basic research community to determine the reporting standards best suited to this kind of research," Congress said.